

Appendix G

8440656



THE UNITED STATES OF AMERICA

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UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

December 13, 2023

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Certified by

Kathi

Performing the Functions and Duties of the
Under Secretary of Commerce
for Intellectual Property
and Director of the United States
Patent and Trademark Office

REMARKS

The following remarks are in response to the Examiner's Final Office Action mailed on July 19, 2012 and Advisory Action of October 12, 2012. Claims 1, 2, 12, and 22 are amended. Claim 23 is new. Support for claim amendments can be found in the application as filed, and specifically, Claim 23 support can be found in Claim 22 as originally filed. Claims 1-23 are pending.

Applicants wish to sincerely thank Examiner Lannu for indication that Applicants' Office Action Response of September 10, 2012 overcame the provisional obviousness type double patenting rejection of the Final Office Action mailed on July 19, 2012. Reconsideration of the Amended Claims is respectfully requested in light of the following remarks.

Interview Summary

Applicants wish to thank the Office for the Telephone Interview on December 19, 2012, which included Applicants' representative, Kristin Havranek, Examiner Joshua Lannu and Primary Examiner John Lacyk, and for the follow up conversation on January 15, 2013, which included Applicants' representative, Kristin Havranek and Examiner Joshua Lannu. The substance of the Advisory Action of October 12, 2012, the Office Action Response of September 10, 2012, and the Final Office Action of Final Office Action mailed on July 19, 2012 were discussed during the Interview and follow up conversation, and it was agreed that the amendments presented herein would place all claims in condition of allowance, for the reasons set forth below, at least.

Double Patenting Rejection

Claims 1 and 3-11 have been provisionally rejected as being unpatentable over claims 1-4 and 6-14 of copending Application No. 12/237,328. Claims 12-16 and 18-21 have been provisionally rejected as being unpatentable over claim 26-33 of copending Application No. 12/237,319. In response, on September 10, 2012, Applicants submitted terminal disclaimers which obviated the provisional nonstatutory double patenting rejections. Withdrawal of such rejections is respectfully requested. As there are no rejections of Claim 1 other than the provisional nonstatutory double patenting rejections, Applications submit that the terminal disclaimers filed puts this claim, at least, in condition of allowance. Thus, Applicants thank the Examiner for the indication of allowance of Claim 1.

Claim Rejections – 35 USC § 102

Claims 2-5 and 22 have been rejected under 35 U.S.C. 102 as being anticipated by US 6,488,617 (“Katz”).

Katz fails to anticipate the elements of Claims 2-5 and 22, at least. Katz describes a feedback system, which in real time, tries to move a subject from a current brain state into a desired brain state via magnetic stimulation. Brain states targeted in Katz are categorized based on the level of alertness of the subject. (Col. 1, line 14 to 34). These states include sleep states associated with brain wave frequencies in the delta and theta ranges of 1.5 to 3.5 Hz and 3.5 to 7 Hz, respectively, a relaxed state associated with brain wave frequencies in the alpha range of 7.5 to 12.5 Hz, and an excited state associated with brain wave frequencies in the beta range of 12.5 to 20 Hz (*Id.*, *See also*, Col. 6, lines 16-35). Thus, each state of Katz is within a different EEG band, and Katz tries to move the subject from one state (in one band) to another state (in another band). At least the following distinctions can be made from the present claims.

With respect to Claim 2, Katz fails to teach or suggest “moving at least one of: an intrinsic frequency of a brain of the subject within a specified EEG band toward a pre-selected intrinsic frequency within the same specified EEG band and a Q-factor of the intrinsic frequency.”

In contrast, Katz targets a desired brain state, which encompasses a range of frequencies in multiple bands. Claim 2 of the present invention targets a pre-selected intrinsic frequency, not a state encompassing a range of frequencies. The Office Action tacitly acknowledges this difference by referring to the desired state of Katz and frequencies in each state, as opposed to a particular pre-selected frequency as is claimed.

Further, Claim 2 of the present invention recites moving the subject’s intrinsic frequency in a specified EEG band toward a pre-selected intrinsic frequency of the same EEG band. On the other hand, Katz’s only intention and goal is to move a subject from a current brain state into a desired brain state. Since the brain states correlate to separate EEG bands in Katz (i.e. from relaxed in the alpha band to sleep in the delta or theta band), Katz’ methods and devices move the brain waves from one band to another.

Alternatively, or additionally, Claim 2 moves a Q factor of an intrinsic frequency. As described and shown in the instant specification (for example at paragraphs [0300], [0326] and in Figure 12, at least), a Q-factor is a measure of the distribution around the frequency within a single

EEG band. Changing a frequency from one band to another band does not inherently or necessarily change the Q-factor, which is essentially a distribution around a particular frequency. In contrast, Katz makes no effort or disclosure regarding the Q-factor or other distribution of frequencies around an intrinsic frequency.

The Office Action points to Katz Column 6 lines 16-61 and states “Katz states that a higher magnitude magnetic field increases the focus of a mean frequency, which is the equivalent of modifying the bandwidth of an intrinsic frequency to a preselected bandwidth.” On the contrary, Katz’s reference to focus refers to the focal area of the brain, and not a focus of a mean frequency. Katz actually says that “a key component [of the magnetic field] is field strength. Greater magnitude [of field strength] implies more influence on the intended [focal area of the brain], although the size of that [focal area] will also increase as the magnitude [of field strength] increases” in Column 6 lines 16-61. This makes sense, since Katz uses multiple magnets having unique and varying frequencies, magnitudes, positions and durations applied to the subject’s head. Thus, Katz recognizes that field strength is one parameter (of several) that may be used in order to achieve its goal of moving a subject from a state in one EEG band to a state in another EEG band; however, Katz neither discloses nor suggests “moving ... a Q-factor of the intrinsic frequency.”

Likewise, for similar reasons as noted with regard to Claims 2, Katz simply fails to disclose or suggest all of the elements of each of Claims 3-5, at least.

Furthermore, neither does Katz disclose or suggest a magnetic field generator of Claim 22 comprising a processor “that moves an intrinsic frequency of a specified EEG band of the subject within the specified EEG band toward a target intrinsic frequency in the specified EEG band, a Q-factor of the intrinsic frequency, a coherence value of intrinsic frequencies among multiple sites in a brain of the subject within a specified EEG band toward a target coherence value wherein if the coherence value is higher than the target coherence value, applying at least two asynchronous magnetic fields close to the head of the subject, and wherein if the coherence value is lower than the target coherence value, applying at least one synchronized magnetic field close to a head of the subject; and an EEG phase between two sites in the brain of a subject of a specified EEG frequency toward a target EEG phase of the specified EEG frequency wherein the magnetic field comprises one or more magnetic field generators that are of the same frequency and are in-phase with each other, of the same frequency and out of phase with each other, or a combination thereof.”

Based on this, at least, Applicants submit the independent Claims 1, 2 (as amended), and 22 (as amended) and all claims dependent therefrom, are in condition for allowance and advancement to allowance is earnestly solicited.

Claim Rejections - 35 USC § 103

Claim 6 has been rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,488,617 (“Katz”) as applied to claim 2, and further in view of 6,001,055 (“Souder”). Claims 7 and 8 have been rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,488,617 (“Katz”) and US 6,001,055 (“Souder”) as applied to claim 6, and further in view of US 5,667,469 (“Zhang”). Claims 9 and 10 have been rejected under 35 U.S.C. 103(a) as being unpatentable over 6,488,617 (“Katz”) as applied to claim 2, and further in view of US 5,788,624 (“Lu”). Claim 11 has been rejected under 35 U.S.C. 103(a) as being unpatentable over 6,488,617 (“Katz”) as applied to claim 2, and further in view of US 3,821,949 (“Hartzell”).

To establish a *prima facie* case of obviousness, the cited art itself or “the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]” at the time of the invention are to have taught or suggested the claim elements. *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1742 (2007); *See also* MPEP § 2143.03. Thus, the Examiner must make “a searching comparison of the claimed invention – including all its limitations – with the teaching of the prior art.” *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995). As such, “obviousness requires a suggestion of all limitations in a claim.” *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)).

As noted above with regard to Claims 2, Katz fails to disclose or suggest all of the elements in each of the noted independent claim. None of Souder, Zhang, Lu, or Hartzell, whether considered alone or in any combination with Katz or any other reference make up for the deficiencies of Katz, as noted above. Thus, Applicants submit that independent Claim 2, and all claims dependent therefrom, are in condition of allowance. Advancement to allowance is earnestly solicited for all of Claims 1 to 11.

Claims 12-21 have been rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,001,055 (“Souder”) and in view of US 6,488,617 (“Katz”). On the contrary, Souder fails to

disclose or suggest a device comprising “a means for applying a magnetic field to a head of a subject; whereby the means for applying the magnetic field comprises a first processor that controls the application of the magnetic field and the first processor or a second processor that moves_at least one of: (a) an intrinsic frequency of a brain of the subject within a specified EEG band; (b) a Q-factor of an intrinsic frequency of the brain of the subject within a specified EEG band; (c) a coherence value of intrinsic frequencies among multiple sites in the brain of the subject within a specified EEG band wherein if the coherence value is higher than a pre-selected coherence value, applying at least two asynchronous magnetic fields close to the head of the subject, and wherein if the coherence value is lower than the pre-selected coherence value, applying at least one synchronized magnetic field close to a head of the subject; and (d) a EEG phase between two sites in the brain of the subject of a specified EEG frequency wherein the magnetic field comprises a first magnetic field that is in-phase with a second magnetic field or a first magnetic field that is out of phase with a second magnetic field” as required in Claim 12, as amended, and thus, required in any claim dependent therefrom. Katz fails to make up for the deficiencies of Souder as noted with regard to Claims 2 or 22, above. Based on this, at least, Applicants submit the independent Claim 12, as amended, and all claims dependent therefrom, are in condition for allowance and advancement to allowance is earnestly solicited.

Attorney Docket No. 35784-706.201

CONCLUSION

In light of the remarks set forth above, Applicants believe that the pending claims are under condition for allowance. Applicants respectfully solicit the Examiner to expedite the prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned.

The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 23-2415 (Attorney Docket No. 35784-706.201).

Respectfully submitted,

Date: January 18, 2013

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REMARKS

The following remarks are in response to the Examiner's Office Action mailed on October 13, 2011. Claims 1, 2, 12, and 21 are amended. Claim 22 is new. Support for all claim amendments and the new claim can be found in the application and claims as filed. Support for amendments to Claims 1, 12, 22 can be found in paragraphs [0184] to [0185], and [0262] to [0266], at least. Support for amendments to Claim 2 can be found throughout the specification as filed, for example paragraph [0014], and [0183], at least. Claims 1-22 are pending with the entry of the above- noted claims. Reconsideration is respectfully requested in light of the following remarks.

Provisional Double Patenting

Claims 1 and 3-11 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-4 and 6-14 of co-pending U.S. Application No. 12/237,328. Claims 12-16 and 18-21 were also provisionally rejected as being unpatentable over claims 26-33 of co-pending U.S. Application No. 12/237,319. While Applicants do not necessarily agree with the position taken by the Examiner, Applicants request that such provisional rejection be held in abeyance and Applicants will consider submitting a terminal disclaimer or additional arguments at the appropriate time.

Claim Rejections - 35 USC § 101

Claim 21 was rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter. Applicants thank the examiner for the suggestion regarding the amendment that would be appropriate to overcome this rejection. Applicants have amended Claim 21 in accordance with this suggestion.

Claim Rejections – 35 USC § 102

Claims 1-5 were rejected under 35 U.S.C. 102(b) as being anticipated by USPN 6,488,617 (Katz). Applicants traverse, for at least the reasons stated below.

Katz fails to anticipate the elements of Claims 1 and 2, at least. Katz describes a feedback system, which in real time, tries to move a subject from a current brain state into a desired brain state via magnetic stimulation. Brain states targeted in Katz are categorized based

on the level of alertness of the subject. (Col. 1, line 14 to 34). These states include sleep states associated with brain wave frequencies in the delta and theta ranges of 1.5 to 3.5 Hz and 3.5 to 7 Hz, respectively, a relaxed state associated with brain wave frequencies in the alpha range of 7.5 to 12.5 Hz, and an excited state associated with brain wave frequencies in the beta range of 12.5 to 20 Hz (*Id.*, *See also*, Col. 6, lines 16-35). Thus, each state of Katz is within a different EEG band, and Katz tries to move the subject from one state (in one band) to another state (in another band). At least the following distinctions can be made from the present claims.

With respect to Claim 1, Katz fails to teach or suggest “adjusting output of a magnetic field to a setting that is operable to ...influence an intrinsic frequency of a specified EEG band of the subject toward a target intrinsic frequency of the specified EEG band.”

In contrast, Katz targets a desired brain state, which encompasses a range of frequencies in multiple bands. Claim 1 of the present invention provides for adjusting a magnetic field output to a setting operable to influence an intrinsic frequency of a specified EEG band of the subject toward a target intrinsic frequency, not toward a state encompassing a range of frequencies. The Office Action tacitly acknowledges this difference by referring to the desired state of Katz and frequencies in each state, as opposed to a particular target frequency as is claimed.

Further, Claim 1 of the present invention recites adjusting output of a magnetic field to influence the subject’s intrinsic frequency in a specified EEG band toward a target intrinsic frequency of the same EEG band. On the other hand, Katz’s only intention and goal is to move a subject from a current brain state into a desired brain state. Since the brain states correlate to separate EEG bands in Katz (i.e. from relaxed in the alpha band to sleep in the delta or theta band), Katz’ methods and devices move the brain waves from one band to another.

Also with respect to Claim 1, since Katz is concerned with moving the current brain state to another brain state, Katz fails to teach or suggest “adjusting output of a magnetic field to a setting that is operable to...influence a Q-factor of the intrinsic frequency toward a target Q-factor.” As described and shown in the instant specification (for example at paragraphs [0313], and in Figure 12, at least), a Q-factor is a measure of the distribution around the frequency within a single EEG band.

The Office Action points to Katz Column 6 lines 16-61 and states “Katz states that a higher magnitude magnetic field increases the focus of a mean frequency, which is the equivalent of modifying the bandwidth of an intrinsic frequency to a preselected bandwidth.” On the contrary,

Katz's reference to focus refers to the focal area of the brain, and not a focus of a mean frequency. Katz actually says that "a key component [of the magnetic field] is field strength. Greater magnitude [of field strength] implies more influence on the intended [focal area of the brain], although the size of that [focal area] will also increase as the magnitude [of field strength] increases" in Column 6 lines 16-61. This makes sense, since Katz uses multiple magnets having unique and varying frequencies, magnitudes, positions and durations applied to the subject's head. Thus, Katz recognizes that field strength is one parameter (of several) that may be used in order to achieve its goal of moving a subject from a state in one EEG band to a state in another EEG band; however, Katz neither discloses nor suggests "adjusting output of a magnetic field for influencing a Q-factor of an intrinsic frequency within a specified EEG band of the subject toward a pre-selected Q-factor."

Further with respect to Claim 1, as amended, Katz fails to teach or suggest "adjusting output of a magnetic field to a setting that is operable to ...influence a coherence value of intrinsic frequencies among multiple sites in a brain of the subject within a specified EEG band toward a target coherence value wherein if the coherence value is higher than the target coherence value, applying at least two asynchronous magnetic fields close to the head of the subject, and wherein if the coherence value is lower than the target coherence value, applying at least one synchronized magnetic field close to a head of the subject."

The Examiner refers to a definition of "coherence" in the Office Action based on Katz. However, Applicants respectfully disagree with this characterization of the term based on the way the term is used in the claims and specification herein. Coherence, as used in the present application, refers to how closely matched are the intrinsic frequencies among multiple sites in a brain of the subject within a specified EEG band (e.g., how closely matched is a first intrinsic frequency of a first site in the brain of the subject within a specified EEG band to a second intrinsic frequency of a second site in the brain of the subject within the same EEG band, at least). (See, e.g. para [0169], at least). It is expressed as a coherence value. Thus, if the two or more intrinsic frequencies are matched in frequency, a coherence value shows this matching characteristic. Likewise, if the two or more intrinsic frequencies are not matched, the coherence value expresses this. A coherence value that is higher (more coherent) would indicate that the intrinsic frequencies are more closely matched than the situation in which a coherence value is lower (indicating less coherent). Accordingly, the method is written such that the subject's own coherence value may shifted up or down-- toward a pre-selected coherence value.

Katz fails to disclose or suggest this method, or a device adapted to achieve this. First, Katz fails to disclose or suggest providing a pre-selected coherence value. Second, Katz also fails to disclose or suggest determining a coherence value of the intrinsic frequencies among multiple sites in a brain of the subject within a specified EEG band. Third, Katz fails to disclose or suggest adjusting output of a magnetic field to a setting that is operable to ...influence a coherence value of intrinsic frequencies among multiple sites in a brain of the subject within a specified EEG band toward a target coherence value wherein if the coherence value is higher than the target coherence value, applying at least two asynchronous magnetic fields close to the head of the subject, and wherein if the coherence value is lower than the target coherence value, applying at least one synchronized magnetic field close to a head of the subject. Rather, Katz expresses a goal of achieving **symmetry in magnitude** of the EEG readings starting with asynchronous magnetic fields (0.5Hz, 5Hz). (See, Column 8 line 39-60, at least). Thus, any **secondary** preference toward coherent waves appears to use **asynchronous magnetic fields** to achieve coherent waves. (See, Column 8 line 39-60, at least). This is different with respect to how fields are used in Claim 1 to influence coherence toward the pre-selected coherence value.

Further, other examples in Katz (e.g. Column 8 lines 60- Column 9 line 16), again refer to the use of the methods and devices of Katz using synchronization “causing the mind to move [from a relaxed state] to a state of alert readiness.” In Katz, this is achieved with “a larger magnet set,” however, it is undisclosed in Katz how synchronization is achieved, i.e., what field distribution would achieve this. (Id.) In fact, Katz is a feedback system that adjusts based on a subject’s reaction to a particular field, and Katz indicates this “will vary from patient to patient.” Thus, Katz again fails to disclose the method of Claim 1, which describes a particular method and field arrangement to use based on the subject’s coherence value and the target coherence value, neither of which Katz discloses or suggests.

For similar reasons as noted with regard to coherence as noted above, Katz simply fails to disclose or suggest other elements of Claim 1, including “adjusting output of a magnetic field to a setting that is operable to ...influence an EEG phase between two sites in the brain of a subject of a specified EEG frequency toward a target EEG phase of the specified EEG frequency wherein the magnetic field comprises one or more magnetic field generators that are of the same frequency and are in-phase with each other, of the same frequency and out of phase with each other, or a combination thereof.”

Likewise, for similar reasons as noted with regard to Claims 1, Katz simply fails to disclose or suggest all of the elements of Claim 2. In particular, Katz fails to disclose or suggest “adjusting an intrinsic frequency of a brain of the subject within a specified EEG band by applying a magnetic field close to a head of the subject, wherein the magnetic field comprises at least one of (a) a single target frequency within the specified EEG band; (b) a plurality of frequencies within the specified EEG band; and (c) the intrinsic frequency of a brain of the subject within the specified EEG band”

Again, Katz targets a desired brain state, which encompasses a range of frequencies in multiple bands. Claim 2 of the present invention provides for applying a magnetic field output that adjusts an intrinsic frequency of a specified EEG band of the subject by applying one or more of: a single target frequency in the same EEG band as the intrinsic frequency, a plurality of frequencies within the same EEG band as the intrinsic frequency, and the intrinsic frequency of a brain of the subject within the same EEG band as the intrinsic frequency. As Katz attempts to move the subject outside of a measured state into another state, this is necessarily targeting moving the brain waves from one band to another. Thus, there is no disclosure or suggestion in Katz of a particular specific method that would achieve this which uses the same method as described and enabled in the present claim.

Based on the above, at least, Applicants submit the independent Claims 1 and 2, as amended, and all claims dependent therefrom, are in condition for allowance and advancement to allowance is earnestly solicited.

Claim Rejections - 35 USC § 103

Claim 6 was rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 6,488,617 (Katz) as applied to claim 1 above, and further in view of USPN 6,001,055 (Souder). Claims 7 and 8 were rejected under 35 U.S.C. 103(a) as being unpatentable over Katz and Souder as applied to claim 6 above and further in view of USPN 5,667,469 (Zhang). Claims 9 and 10 were rejected under 35 U.S.C. 103(a) as being unpatentable over Katz as applied to claim 1 above, and further in view of USPN 5,788,624 (Lu). Claim 11 was rejected under 35 U.S.C. 103(a) as being unpatentable over Katz as applied to claim 1 above, and further in view of USPN 3,821,949 (Hartzell).

To establish a *prima facie* case of obviousness, the cited art itself or “the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]” at the time of the

invention are to have taught or suggested the claim elements. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1742 (2007); *See also* MPEP § 2143.03. Thus, the Examiner must make “a searching comparison of the claimed invention – including all its limitations – with the teaching of the prior art.” *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995). As such, “obviousness requires a suggestion of all limitations in a claim.” *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)).

As noted above with regard to Claims 1 and 2, Katz fails to disclose or suggest all of the elements in each of the noted independent claims. None of Souder, Zhang, Lu, and Hatzell, whether considered alone or in any combination with Katz or any other reference make up for the deficiencies of Katz, as noted above. Thus, Applicants submit that independent Claims 1, and 2, and all claims dependent therefrom, are in condition of allowance. Advancement to allowance is earnestly solicited for all of Claims 1 to 11.

Claims 12-21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Souder in view of Katz. As suggested in the Office Action, Souder fails to disclose or suggest a device comprising “a means for applying a magnetic field to a head of a subject; whereby the means for applying the magnetic field is configured to influence at least one of: (a) an intrinsic frequency of a brain of the subject within a specified EEG band; (b) a Q-factor of an intrinsic frequency of the brain of the subject within a specified EEG band; (c) a coherence value of intrinsic frequencies among multiple sites in a the brain of the subject within a specified EEG band wherein if the coherence value is higher than a pre-selected coherence value, applying at least two asynchronous magnetic fields close to the head of the subject, and wherein if the coherence value is lower than the pre-selected coherence value, applying at least one synchronized magnetic field close to a head of the subject; and (d) a EEG phase between two sites in the brain of the subject of a specified EEG frequency wherein the magnetic field comprises a first magnetic field that is in-phase with a second magnetic field or a first magnetic field that is out of phase with a second magnetic field.” For similar reasons as noted with regard to Claim 1, above, Katz fails to make up for the deficiencies of Souder. Whether considered alone or in combination, both Souder and Katz fail to disclose or suggest all of the elements of Claim 12.

As noted above, Katz moves a subject **from a current brain state into a desired brain state**. Since the brain states correlate to separate EEG bands in Katz (i.e. from relaxed in the

alpha band to sleep in the delta or theta band), Katz' methods and devices move the brain waves from one band to another. This fails to disclose or suggest a device configured to influence a subject's intrinsic frequency within **a specified EEG band**.

Further, Katz fails to disclose or suggest a device that is configured to influence a Q-factor. The sections of Katz referred to in the Office Action misconstrue the word "focus" to mean a distribution around a frequency. On the contrary, Katz uses the term "focus" to refer to the "focal area of the brain." This is supported by Katz and technically justified based on Katz itself, at least, since when an increased magnitude of field strength is applied to a location on the brain of a subject, the focal area of the field brain likewise increases (i.e., the field reaches farther, wider into the brain of the subject). Thus, Katz fails to provide or suggest a device configured to influence a Q-factor.

Likewise, Katz fails to provide or suggest a device configured influence a subject's coherence value to lower or raise the coherence value as claimed, since Katz expresses a goal of achieving **symmetry in magnitude** of the EEG readings starting with asynchronous magnetic fields (0.5Hz, 5Hz). Thus, any **secondary** preference toward coherent waves appears to also use **asynchronous magnetic fields**. (See, Column 8 line 39-60, at least). This is different with respect to how fields are configured in Claim 12 to influence the subject's coherence value toward the pre-selected coherence value.

Furthermore, Katz fails to provide or suggest a device configured to influence an EEG phase between two sites in the brain of the subject of a specified EEG frequency wherein the magnetic field comprises a first magnetic field that is in-phase with a second magnetic field or a first magnetic field that is out of phase with a second magnetic field for similar reasons as noted above, at least.

In sum, since neither Souder nor Katz disclose or suggest all of the elements of Claim 12, this claim is in condition of allowance. So to, therefore, are all claims dependent from Claim 12 in condition of allowance. Advancement to allowance is earnestly solicited for all of Claims 12 to 21.

Attorney Docket No. 35784-706.201
(formerly: 35784-701.202)

CONCLUSION

In light of the remarks set forth above, Applicants believe that the pending claims are under condition for allowance. Applicants respectfully solicit the Examiner to expedite the prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned.

The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit account No. 23-2415 (Attorney Docket No. 32695-706.201).

Respectfully submitted,

Date: March 12, 2012

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REMARKS

The following remarks are in response to the Examiner's Final Office Action mailed on July 19, 2012. Claims 2, 12, and 22 are amended. Claim 23 is new. Support for claim amendments can be found in the application as filed, and specifically, Claim 23 support can be found in Claim 22 as originally filed. Claims 1-23 are pending. Reconsideration is respectfully requested in light of the following remarks.

Double Patenting Rejection

Claims 1 and 3-11 have been provisionally rejected as being upatentable over claims 1-4 and 6-14 of copending Application No. 12/237,328. Claims 12-16 and 18-21 have been provisionally rejected as being upatentable over claim 26-33 of copending Application No. 12/237,319. In response, Applicants herewith submit terminal disclaimers which obviate the provisional nonstatutory double patenting rejections. Withdrawal of such rejections is respectfully requested. As there are no rejections of Claim 1 other than the provisional nonstatutory double patenting rejections, Applicants submit that the terminal disclaimers filed puts this claim, at least, in condition of allowance. Thus, Applicants thank the Examiner for the indication of allowance of Claim 1.

Claim Rejections – 35 USC § 102

Claims 2-5 and 22 have been rejected under 35 U.S.C. 102 as being anticipated by US 6,488,617 ("Katz").

Katz fails to anticipate the elements of Claims 2-5 and 22, at least. Katz describes a feedback system, which in real time, tries to move a subject from a current brain state into a desired brain state via magnetic stimulation. Brain states targeted in Katz are categorized based on the level of alertness of the subject. (Col. 1, line 14 to 34). These states include sleep states associated with brain wave frequencies in the delta and theta ranges of 1.5 to 3.5 Hz and 3.5 to 7 Hz, respectively, a relaxed state associated with brain wave frequencies in the alpha range of 7.5 to 12.5 Hz, and an excited state associated with brain wave frequencies in the beta range of 12.5 to 20 Hz (*Id.*, See also, Col. 6, lines 16-35). Thus, each state of Katz is within a different

EEG band, and Katz tries to move the subject from one state (in one band) to another state (in another band). At least the following distinctions can be made from the present claims.

With respect to Claim 2, Katz fails to teach or suggest “influencing at least one of: an intrinsic frequency of a brain of the subject within a specified EEG band toward a pre-selected intrinsic frequency within the same specified EEG band and a Q-factor of the intrinsic frequency within the same specified EEG band.”

In contrast, Katz targets a desired brain state, which encompasses a range of frequencies in multiple bands. Claim 2 of the present invention targets a pre-selected intrinsic frequency, not a state encompassing a range of frequencies. The Office Action tacitly acknowledges this difference by referring to the desired state of Katz and frequencies in each state, as opposed to a particular pre-selected frequency as is claimed.

Further, Claim 2 of the present invention recites adjusting output of a magnetic field and influencing the subject’s intrinsic frequency in a specified EEG band toward a pre-selected intrinsic frequency of the same EEG band. On the other hand, Katz’s only intention and goal is to move a subject from a current brain state into a desired brain state. Since the brain states correlate to separate EEG bands in Katz (i.e. from relaxed in the alpha band to sleep in the delta or theta band), Katz’ methods and devices move the brain waves from one band to another.

Alternatively, or additionally, Claim 2 targets a Q factor of an intrinsic frequency within a single EEG band (the “specified EEG band”). As described and shown in the instant specification (for example at paragraphs [0300], [0326] and in Figure 12, at least), a Q-factor is a measure of the distribution around the frequency within a single EEG band. Changing a frequency from one band to another band does not inherently or necessarily change the Q-factor, which is essentially a distribution around a particular frequency. In contrast, Katz makes no effort or disclosure regarding the Q-factor or other distribution of frequencies around an intrinsic frequency.

The Office Action points to Katz Column 6 lines 16-61 and states “Katz states that a higher magnitude magnetic field increases the focus of a mean frequency, which is the equivalent of modifying the bandwidth of an intrinsic frequency to a preselected bandwidth.” On the contrary, Katz’s reference to focus refers to the focal area of the brain, and not a focus of a mean frequency. Katz actually says that “a key component [of the magnetic field] is field strength. Greater magnitude

[of field strength] implies more influence on the intended [focal area of the brain], although the size of that [focal area] will also increase as the magnitude [of field strength] increases” in Column 6 lines 16-61. This makes sense, since Katz uses multiple magnets having unique and varying frequencies, magnitudes, positions and durations applied to the subject’s head. Thus, Katz recognizes that field strength is one parameter (of several) that may be used in order to achieve its goal of moving a subject from a state in one EEG band to a state in another EEG band; however, Katz neither discloses nor suggests “adjusting output of a magnetic field ... and influencing a Q-factor of an intrinsic frequency within a specified EEG band of the subject toward a pre-selected Q-factor.”

Likewise, for similar reasons as noted with regard to Claims 2, Katz simply fails to disclose or suggest all of the elements of each of Claims 3-5 and 22, at least. Based on the above, at least, Applicants submit the independent Claims 1, 2 (as amended), and 22 (as amended) and all claims dependent therefrom, are in condition for allowance and advancement to allowance is earnestly solicited.

Claim Rejections - 35 USC § 103

Claim 6 has been rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,488,617 (“Katz”) as applied to claim 2, and further in view of 6,001,055 (“Souder”). Claims 7 and 8 have been rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,488,617 (“Katz”) and US 6,001,055 (“Souder”) as applied to claim 6, and further in view of US 5,667,469 (“Zhang”). Claims 9 and 10 have been rejected under 35 U.S.C. 103(a) as being unpatentable over 6,488,617 (“Katz”) as applied to claim 2, and further in view of US 5,788,624 (“Lu”). Claim 11 has been rejected under 35 U.S.C. 103(a) as being unpatentable over 6,488,617 (“Katz”) as applied to claim 2, and further in view of US 3,821,949 (“Hartzell”).

To establish a *prima facie* case of obviousness, the cited art itself or “the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]” at the time of the invention are to have taught or suggested the claim elements. *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1742 (2007); *See also* MPEP § 2143.03. Thus, the Examiner must make “a searching comparison of the claimed invention – including all its limitations – with the teaching of the prior art.” *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995). As such, “obviousness requires a

suggestion of all limitations in a claim.” *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)).

As noted above with regard to Claims 2, Katz fails to disclose or suggest all of the elements in each of the noted independent claim. None of Souder, Zhang, Lu, or Hartzell, whether considered alone or in any combination with Katz or any other reference make up for the deficiencies of Katz, as noted above. Thus, Applicants submit that independent Claim 2, and all claims dependent therefrom, are in condition of allowance. Advancement to allowance is earnestly solicited for all of Claims 1 to 11.

Claims 12-21 have been rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,001,055 (“Souder”) and in view of US 6,488,617 (“Katz”). On the contrary, Souder fails to disclose or suggest a device comprising “a means for applying a magnetic field to a head of a subject; whereby the means for applying the magnetic field comprises a processor or logic that controls the application of the magnetic field and logic that implements the methods of Claims 1, 2, or a combination thereof ” as required in Claim 12, as amended, and thus, required in any claim dependent therefrom. Katz fails to make up for the deficiencies of Souder as noted with regard to Claims 2 or 22, above. Based on this, at least, Applicants submit the independent Claim 12, as amended, and all claims dependent therefrom, are in condition for allowance and advancement to allowance is earnestly solicited.

Attorney Docket No. 35784-706.201

CONCLUSION

In light of the remarks set forth above, Applicants believe that the pending claims are under condition for allowance. Applicants respectfully solicit the Examiner to expedite the prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned.

The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 23-2415 (Attorney Docket No. 35784-706.201).

Respectfully submitted,

Date: September 10, 2012

By: /Kristin Havranek/
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EXAMINER

LANNU, JOSHUA DARYL DEANON

ART UNIT	PAPER NUMBER
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3735

MAIL DATE	DELIVERY MODE
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10/13/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

12/850,547

Applicant(s)

PHILLIPS ET AL.

Examiner

JOSHUA D. LANNU

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-21 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-21 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 04 August 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/6/2011, 2/3/2011, 12/13/2010, 10/2/2010</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Double Patenting

Claims 1 and 3-11 of this application conflict with claims 1-4 and 6-14 of Application No. 12237328. Claims 12-16 and 18-21 of this application conflict with claims 26-33 of Application No. 12237319. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 3-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 6-14 of copending Application No. 12237328. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application discloses the same method for treating depression, which is associated with Post Traumatic Stress Disorder (PTSD). Because depression is associated with PTSD, the method proposed in the copending application anticipates the method's use in treating a subject for PTSD.

Claims 12-16 and 18-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-33 of copending Application No. 12,237,319. Although the conflicting claims are not identical, they are not patentably distinct from each other because the device specified in claims 26-33 of the copending application are more specific and anticipate the more general form of the device, which is proposed in claims 16-20 and 22-25 of the current application.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 21 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 21 recites that “the second electrode is located on the subject”. This recites a positive relationship to the human body. However, the human body is non-statutory subject matter and cannot be positively recited. Therefore, Applicant should amend the claim to recite that --the second electrode is adapted to be located on the subject--.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 - 5 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,488,617 (Katz).

In regards to claim 1, Katz discloses a method that influences EEG frequencies in the brain by applying a magnetic field close to the head of a subject. Katz states that the invention disclosed executes steps to influence intrinsic frequencies of EEG bands to a desired state via

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magnetic stimulation (column 6 lines 16-61). Katz discloses the algorithm that is executed by a computational system that adjusts parameters of magnetic stimulation until the distance between the desired EEG signal and the actual EEG signal is minimized (column 7 lines 26-63). Katz also shows in figure 2 a system with magnets that apply the magnetic field to the head of the subject (column 6 line 62 – column 7 line 18). Katz further states in claim 15 that the method is used to treat depression, which is associated with PTSD. Q-factor is being interpreted as the bandwidth about a center frequency. Katz discloses a method for treating depression (claim 15) that influences EEG frequencies in the brain by applying a magnetic field close to the head of a subject. Katz states that a higher magnitude magnetic field increases the focus of a mean frequency, which is the equivalent of modifying the bandwidth of an intrinsic frequency to a preselected bandwidth (column 6 lines 16-61). Coherence is defined as waves with the same frequency and in phase. Katz discloses a method that influences EEG frequencies in the brain by applying a magnetic field close to the head of a subject by stimulation along multiple sites in a brain of a subject (figure 2). Katz shows the method of stimulating multiple sites in figure 2 as well as influencing coherence from multiple sites in the brain to get to a state of relaxation, which is correlated to the strength of the alpha band (column 8 line 39- column 9 line 16).

In regards to claim 2, Katz discloses a method for treating depression, which is associated with PTSD. Katz discloses the step of applying a magnetic field close to the head of a subject (figure 2) to induce a desired frequency which is correlated to a particular brain state (column 6 lines 16-61). Katz further states inducing states of relaxation, which in essence is adjusting the intrinsic frequency of a subject (the actual frequency) towards a desired frequency to induce the specific brain state (column 8 line 60 – column 9 line 16). Katz further states that

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the magnetic field will pulse at a unique frequency for each magnet to excite or suppress cortical activity (column 6 lines 40-44).

In regards to claims 3-5 Katz discloses all elements of claim 1. In addition, Katz states the step of measuring EEG data after the application of the magnetic field in claim 21. Katz discloses the step of adjusting parameters of the magnetic field and repeating the applying step with an adjusted parameter in claim 21. Katz further states that pulse frequency of the magnetic field is one of the parameters (column 6 lines 45-54). Katz also teaches the application of a larger magnet set to achieve large scale synchronization of two hemispheres (column 8 line 39 – column 9 line 16), which is interpreted as the application of a magnetic field over a diffuse area of the brain. Katz also states that frequencies between 1.5 Hz and 7.5 Hz induce a specific type of intrinsic frequency band (column 6 lines 29-34) and further states that frequencies below 1 Hz suppress activity while frequencies about 1 Hz excite the cortex.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,488,617 (Katz) as applied to claim 1 above, and further in view of US 6,001,055 (Souder).

In regards to claim 6, Katz discloses all limitations of claims 1. However Katz does not use a permanent magnet to generate the magnetic field for magnetic therapy in the mentioned method. Souder discloses the use of a magnetic therapy device with at least one permanent magnet (element 24 and column 2 lines 58-63). Souder states that a moving magnetic field is generated by the rotation of the permanent magnet and subjects the treatment area to varying intensities of north or south pole fields (column 6 lines 1-36). In addition Souder states that applying the dynamic field enhances the beneficial effects of magnetic therapy (column 1 lines 25-30). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a permanent magnet with rotational motion as taught by Souder in the method of Katz in order to enhance the beneficial effects of magnetic therapy.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,488,617 (Katz) and US 6,001,055 (Souder) as applied to claim 6 above, and further in view of US 5,667,469 (Zhang et al.).

In regards to claims 7 and 8, Katz and Souder disclose the limitations of claim 6. However, Katz and Souder do not explicitly state that the strength of the permanent magnet is from about 10 Gauss to about 4 Tesla nor state that the distance between the permanent magnet and the subject is from about 1/32 inch to about 12 inches. Zhang et al. (hereinafter referred to as

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Zhang) teaches a rotating permanent magnet device for medical therapy. Zhang states that the magnet of the device can generate a magnetic field intensity of about 0.1-0.8 Tesla (column 6 lines 6-24), which falls within the range specified in claim 7. Katz states that increasing the magnitude of the magnetic field implies a greater focus (column 6 lines 40-44). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the permanent magnet with a strength of about 0.1-0.8 Tesla as taught by Zhang in the method disclosed by Katz and Souder in order to increase focus of a magnetic field in a treatment area.

Katz, Souder and Zhang do not address the specific distance of the patient and the magnet. It can be seen in figure 3 of Zhang that the patient is placed on a table with the magnet underneath the table exerting its magnetic field. Zhang states that the treatment diameter can go up to 950 mm/37.4 inches (column 6 lines 6-24). The treatment radius then would be 19.7 inches, where the treatment radius is interpreted as range of distances from the magnet where a patient can be placed. Zhang does not address the range specified. However the treatment diameter of 37.4 inches includes the specified range of 1/32 inch to 12 inches. Applicant has not disclosed that the range specified solves any stated problem or is for any particular purpose. Moreover, it appears that the range used by Katz, Souder, and Zhang or the applicant's invention would perform equally well with applying the magnetic field to the head to influence EEG signals from an actual to a desired state.

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified Katz, Souder, and Zhang such that the range used between the subject and magnet in the method is from about 1/32 inch to about 12 inches because the general conditions of the claim are disclosed in the prior art. Furthermore, it would

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be the natural desire of scientists or artisans to optimize ranges in order to improve on what is generally known.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over 6,488,617 (Katz) as applied to claim 1 above, and further in view of US 5,788,624 (Lu et al.).

In regards to claims 9 and 10, Katz discloses the limitations of claim 1. However Katz makes no mention of the timing of application of the magnetic field. Lu et al. (hereinafter referred to as Lu) discloses a step of administering magnetic field therapy with a duration of 20-40 minutes once each a day for a period of 12 -14 days (column 3 lines 55-64). Lu states that a transient magnetic field does not make a patient uncomfortable and that exposure to a continuous magnetic field may cause other issues such as headaches, insomnia, etc... (column 3 line 65 – column 4 line 14). Lu also states that transient application brings an effective interaction of the blood, body fluids, nervous system, channels, and collaterals of the body within a short period of time (column 2 lines 33-41). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use transient magnetic fields with durations of 20-40 minutes per day over 12-14 days as taught by Lu in the method of Katz in order to provide an effective interaction of blood, body fluids, nervous system, channels, and collaterals of the body.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over 6,488,617 (Katz) as applied to claim 1 above, and further in view of US 3,821,949 (Hartzell et al.).

In regards to claim 11, Katz discloses the limitations of claims 1. Katz teaches the use of a device with magnetic stimulation and EEG recording capabilities to produce a desired brain state. In figure 1 a set of electrodes (element 1) are located on the scalp of the subject to measure the EEG, brain activity, of the individual (column 5 lines 20-33). Electrical resistivity is the

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measure of how strongly a material opposes the flow of electric current. Because all the electrodes are on skin, which allows electric current to flow, the electrodes would be on an area of low electrical resistivity. Electrical impulse interference is essentially noise. Additionally, because the electrodes are on the scalp, the electrodes are in an area with substantially no electrical impulse interference due to the electrical signals being mostly coming from neurons instead of other sources such as eye muscles. All the electrodes are operable to detect brain activity. If one electrode is chosen as the one for detecting brain activity, any of the other electrodes can function as a second electrode that is operable to detect a reference signal. Katz also states the step of determining the mean frequency, an intrinsic frequency, of a subject in order to determine differences between an actual and desired brain state (column 6 lines 16-61). However, Katz does not explicitly state that the intrinsic frequency is determined from the electrical activity from the first electrode and the reference signal detected by the second electrode. Hartzell discloses the specifics of EEG devices. Hartzell specifically outlines the use of a reference electrode (element 38) and an active electrode (element 46) to sense brain wave potentials (column 7 line 55 – column 8 line 14). The biofeedback apparatus (figure 2 element 10a) takes the signals from the active electrode and the reference electrode. The signal is then run through amplifiers and passed through filters for specific frequency ranges to determine the frequencies for alpha, beta, and theta bands (column 8 line 15 – column 9 line 2). Hartzell in particular specifies using the ear lobes as reference and neutral electrodes to sense brain wave potentials (column 8 lines 2-14) It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a reference and source electrode as taught by Hartzell in the method disclosed by Katz in order to detect and sense the brain wave potentials.

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Claims 12-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,001,055 (Souder) and in view of US 6,488,617 (Katz).

In regards to claims 12-17, Souder discloses a device that is used for magnetic therapy. The device extends a magnetic field for application to an anatomical area (see abstract). Souder discloses several device embodiments made of at least one permanent magnet (element 24, column 6 lines 14-16) and a subunit coupled to the magnet that allows the magnet to rotate in a rotational motion (column 6 lines 37-39) such as element 20 in figure 3. Souder states that a moving magnetic field is generated by the rotation of the permanent magnet and subjects the treatment area to varying intensities of north or south pole fields (column 6 lines 1-36). Souder also states that the user is subjected to alternating magnetic fields (column 10 lines 9-15). Souder mentions the concept of making an alternating magnetic field as moving magnets relative to a treatment area (column 5 lines 58-61). Souder also states that the speeds at which the shafts spin the magnets are preferably between 400 – 8000 revolutions per minute (RPMs), which based on RPM to Hz conversions would be between 6.66 Hz and 133.33 Hz (column 8 lines 17-32) which overlaps in the range specified by Applicant. However, Souder does not explicitly disclose that the device is capable of influencing an intrinsic frequency of a brain of the subject within a specified EEG band, a Q-factor of an intrinsic frequency of a brain of the subject within a specified EEG band, a coherence of intrinsic frequencies among multiple sites in a brain of a subject of a specified EEG band, and a phase between two sites in the brain of a subject of a specified EEG frequency. Katz teaches a magnetic therapy device that can be used for treating depression (claim 15). The device of Katz implements a method that uses magnetic fields, as applied to claim 1 of the current application, to influence an intrinsic frequency of a brain of the

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subject within a specified EEG band, a Q-factor if an intrinsic frequency of a brain of the subject within a specified EEG band, a coherence of intrinsic frequencies among multiple sites in a brain of a subject of a specified EEG band, and/or a phase between two sites in the brain of a subject of a specified EEG frequency. Katz further states that being able to influence these EEG frequencies allows improvement of deficient or non-optimal mental states (column 1 lines 57-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a the capability of influencing an intrinsic frequency of a brain of the subject within a specified EEG band, a Q-factor if an intrinsic frequency of a brain of the subject within a specified EEG band, a coherence of intrinsic frequencies among multiple sites in a brain of a subject of a specified EEG band, and a phase between two sites in the brain of a subject of a specified EEG frequency as taught by Katz in the device of Souder in order to improve deficient or non-optimal mental states.

In regards to claims 18, Souder and Katz disclose the limitations of claim 12. Souder also states that the speeds at which the shafts spin the magnets are preferably between 400 – 8000 revolutions per minute (RPMs), which based on RPM to Hz conversions would be between 6.66 Hz and 133.33 Hz (column 8 lines 17-32) which. In addition, Souder states that the device is capable of going to lower frequencies as dictated to get to an optimal frequency (column 8 lines 30-32), which would enable movement to the at the 0.5 Hz frequency. However, Souder does not explicitly state that the device further comprises a logic that controls the frequencies in increments of about 0.1 Hz. Katz teaches the logic (element 7) that controls frequency stimulation. Because the logic is depicted as a computer, it would be capable of controlling frequencies by increments of 0.1 Hz. Katz includes this feature in his system to influence these

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EEG frequencies and allow improvement of deficient or non-optimal mental states (column 1 lines 57-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a logic to control frequency as taught by Katz into the device disclosed by Souder in order to influence EEG frequencies and allow improvement of deficient and non-optimal mental states.

In regards to claims 19 and 20, Souder and Katz disclose all limitations of claim 12, but do not explicitly state that the device is operable to influence or calculate at least one of the following: an intrinsic frequency of the brain of the subject within a specified EEG band; a Q-factor of the at least one intrinsic frequency, coherence values of intrinsic frequencies from multiple sites in the brain of a subject within a specified EEG band; and an EEG phase between two sites in the brain of a subject of a specified EEG frequency. Souder also does not disclose logic that changes the frequency of magnet movement in response to EEG readings of a subject during treatment. Katz discloses a device that influences the intrinsic frequencies of the brain of a subject (column 6 lines 16-35), influence a Q factor of the intrinsic frequency (column 6 lines 16-35), influence coherence of intrinsic frequencies among multiple sites in the brain of a subject within a specified EEG band (column 8 lines 39-59), and influence an EEG phase between two sites in the brain of a subject (column 8 lines 39-59). In addition Katz teaches a logic device (element 7) that automatically changes frequencies in response to an EEG signal (column 6 line 62- column 8 line 5) and calculates intrinsic frequency data, Q-factors of intrinsic frequency, coherence values of intrinsic frequencies and EEG phase from collected EEG data (column 6 lines 16-35). Katz further states that being able to influence these EEG frequencies allows improvement of deficient or non-optimal mental states (column 1 lines 57-65). It would have

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been obvious to one of ordinary skill in the art at the time the invention was made to include a logic that changes magnetic stimulation frequencies and calculate EEG information and influence EEG data as taught by Katz in the device of Souder in order to improve deficient or non-optimal mental states.

In regards to claim 21, Souder and Katz disclose all limitations of claim 12. In addition, Katz teaches a device with magnetic stimulation and EEG recording capabilities to produce a desired brain state. In figure 1 a set of electrodes (element 1) are placed on the scalp of the subject to measure the EEG, brain activity, of the individual (column 5 lines 20-33). All the electrodes are operable to detect brain activity. If one electrode is chosen as the one for detecting brain activity, any of the other electrodes can function as a second electrode to detect a reference signal. Katz shows EEG comparisons to determine coherence between the left and right hemispheres (column 8 lines 39-59), which in essence is a difference or correlation between a signal and a reference signal. Electrical resistivity is the measure of how strongly a material opposes the flow of electric current. Because all the electrodes are on skin, which allows electric current to flow, the electrodes would be on an area of low electrical resistivity. Electrical impulse interference is essentially noise. Because the electrodes are on the scalp, the electrodes are in an area with substantially no electrical impulse interference due to the electrical signals being mostly coming from neurons instead of other sources such as eye muscles. Katz states that having feedback with the therapy allows for the minimization of differences between an actual and desired brain state (see abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the measurement of EEG signals as taught

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by Katz with the magnetic device of Souder in order to determine if the therapy is inducing a desired brain state.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSHUA D. LANNU whose telephone number is (571)270-1986. The examiner can normally be reached on Monday-Friday 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles A. Marmor can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. D. L./
Examiner, Art Unit 3735

/John P Lacyk/
Primary Examiner, Art Unit 3735

Electronically Filed on March 12, 2012

Attorney Docket No. 35784-706.201
(Formerly 35784-701.202)
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: James William Phillips et al.

Serial Number: 12/850,547

Filing Date: August 4, 2010

Title: SYSTEMS AND METHODS FOR
MODULATING THE ELECTRICAL
ACTIVITY OF A BRAIN USING NEURO-
EEG SYNCHRONIZATION THERAPY

Group Art Unit: 3735

Examiner: Lannu, Joshua Daryl Deanon

Confirmation No: 1056

Customer No. 021971

AMENDMENT IN RESPONSE TO OFFICE ACTION

MAIL STOP AMENDMENT

Commissioner for Patents

P.O. Box 1450

Alexandria VA 22313-1450

Madam:

In response to Examiner's Office Action mailed October 13, 2011, Applicants respectfully request reconsideration of the above-referenced application in view of the following amendments and remarks. A Petition for Extension of Time is requested for a reply within the second month and the fee set forth under 37 C.F.R. §1.17(a)(2) is electronically submitted herewith.

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 6 of this paper

Conclusion begins on page 13 of this paper

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings of claims in this application. Applicant reserves the right to pursue any subject matter of any canceled claims in this or any other appropriate patent application. Support for these claims is provided in the remarks following the listing of claims.

1. (Original) A method of treating Parkinson's disease, treating coma, treating post traumatic stress disorder (PTSD), treating amblyopia, and/or enhancing cognitive performance, in a subject, comprising:
 - (a) adjusting output of a magnetic field to a setting that is operable to do ~~for~~ one or more of the following:
 - (1) ~~influence~~ ~~influencing~~ an intrinsic frequency of a specified EEG band of the subject toward a target intrinsic frequency of the specified EEG band,
 - (2) ~~influence for influencing~~ a Q-factor of ~~the an~~ intrinsic frequency ~~within a specified EEG band of the subject~~ toward a target Q-factor,
 - (3) ~~influence~~ ~~influencing~~ a coherence value of intrinsic frequencies among multiple sites in a brain of the subject within a specified EEG band toward a target coherence value wherein if the coherence value is higher than the target coherence value, applying at least two asynchronous magnetic fields close to the head of the subject, and wherein if the coherence value is lower than the target coherence value, applying at least one synchronized magnetic field close to a head of the subject; and
 - (4) ~~influence~~ ~~influencing~~ an EEG phase between two sites in the brain of a subject of a specified EEG frequency toward a target EEG phase of the specified EEG frequency wherein the magnetic field comprises one or more magnetic field generators that are of the same frequency and are in-phase with each other, of the same frequency and out of phase with each other, or a combination thereof; and
 - (b) applying said magnetic field close to a head of the subject.
2. (Currently Amended) A method of treating Parkinson's disease, treating coma, treating post traumatic stress disorder (PTSD), treating amblyopia, and/or enhancing cognitive performance in a subject, comprising adjusting an intrinsic frequency of a brain of the subject within a specified EEG band by applying a magnetic field close to a head of the subject,

wherein the magnetic field comprises at least one of (a) a single target frequency within the specified EEG band; (b) a plurality of frequencies within the a specified EEG band; and (c) ~~an~~ the intrinsic frequency of a brain of the subject within the a specified EEG band wherein adjusting the intrinsic frequency comprises influencing a Q-factor of the intrinsic frequency.

3. (Original) The method of claim 1 or 2, further comprising the step of measuring EEG data of the subject after the applying step.
4. (Original) The method of claim 1 or 2, further comprising the steps of: adjusting frequency of said magnetic field based on the EEG data of the subject; and repeating the applying step with an adjusted frequency.
5. (Original) The method of claim 1 or 2, wherein the applying of the magnetic field applies the magnetic field to a diffuse area in a brain of the subject.
6. (Original) The method of claim 1 or 2, wherein the magnetic field is generated by movement of at least one permanent magnet.
7. (Original) The method of claim 6, wherein the strength of the at least one permanent magnet is from about 10 Gauss to about 4 Tesla.
8. (Original) The method of claim 7, wherein the distance between the at least one permanent magnet and the subject is from about 1/32 in to about 12 in.
9. (Original) The method of claim 1 or 2, wherein the step of applying the magnetic field is for about 5 minutes to about two hours.
10. (Original) The method of claim 1 or 2, further comprising repeating the applying step after an interval about 6 hours to about 14 days.
11. (Original) The method of claim 1 or 2, further comprising: (a) locating a first electrode operable to detect electrical brain activity on the subject in at least one of an area of low electrical resistivity on a subject, and an area with substantially no electrical impulse interference on a subject; (b) locating a second electrode operable to detect a reference signal on the subject; and (c) determining the intrinsic frequency from the electrical brain activity detected by the first electrode and the reference signal detected by the second electrode.
12. (Original) A device for use in treating Parkinson's disease, treating coma, treating post traumatic stress disorder (PTSD), treating amblyopia, and/or enhancing cognitive performance in a subject, comprising: a means for applying a magnetic field to a head of a subject; whereby the means for applying the magnetic field is configured to influence

~~capable of influencing~~ at least one of: (a) an intrinsic frequency of a brain of the subject within a specified EEG band; (b) a Q-factor of an intrinsic frequency of a the brain of the subject within a specified EEG band; (c) a coherence value of intrinsic frequencies among multiple sites in a the brain of the subject within a specified EEG band wherein if the coherence value is higher than a pre-selected coherence value, applying at least two asynchronous magnetic fields close to the head of the subject, and wherein if the coherence value is lower than the pre-selected coherence value, applying at least one synchronized magnetic field close to a head of the subject; and (d) a EEG phase between two sites in the brain of a the subject of a specified EEG frequency wherein the magnetic field comprises a first magnetic field that is in-phase with a second magnetic field or a first magnetic field that is out of phase with a second magnetic field.

13. (Original) The device of claim 12, comprising at least one permanent magnet.
14. (Original) The device of claim 12, wherein the magnetic field is generated by movement of at least one permanent magnet.
15. (Original) The device of claim 12, wherein the movement of the at least one said magnet is at a frequency between about 0.5 Hz and about 100 Hz.
16. (Original) The device of claim 12, wherein said movement comprises at least one of rotational motion, linear motion, and swing motion.
17. (Original) The device of claim 12, wherein said movement generates an alternating magnetic field.
18. (Original) The device of claim 12, further comprising logic that controls the frequency to be any frequency between about 0.5 Hz and about 100 Hz in increments of about 0.1 Hz.
19. (Original) The device of claim 12, further comprising logic that automatically changes the frequency in response to EEG readings of a subject during treatment.
20. (Original) The device of claim 12, further comprising logic that calculates information from EEG data collected from the subject within a specified EEG band, wherein said information comprises at least one of items listed below: (a) at least one intrinsic frequency; (b) Q-factor of the at least one intrinsic frequency; (c) a coherence value of intrinsic frequencies; (d) an EEG phase; and (e) any combination thereof.
21. (Original) The device of claim 12, further comprising: (a) a first electrode operable to detect electrical brain activity; and (b) a second electrode operable to detect a reference signal;

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(formerly: 35784-701.202)

wherein the first electrode adapted to be ~~is~~ located on the subject in at least one of: an area of low electrical resistivity on a subject, and an area with substantially no electrical impulse interference on a subject, and wherein the second electrode adapted to be ~~is~~ located on the subject.

22. (New) A device for treating Parkinson's disease, treating coma, treating post traumatic stress disorder (PTSD), treating amblyopia, and/or enhancing cognitive performance in a subject, comprising a magnetic field generator configured apply a magnetic field close to a head of the subject, wherein the magnetic field is chosen in order to adjust a Q-factor of an intrinsic frequency of a brain of the subject within a specified EEG band by, wherein the magnetic field comprises at least one of (a) a single target frequency within the specified EEG band; (b) a plurality of frequencies within the a specified EEG band; and (c) the intrinsic frequency of a brain of the subject within the a specified EEG band.

REMARKS

The following remarks are in response to the Examiner's Office Action mailed on October 13, 2011. Claims 1, 2, 12, and 21 are amended. Claim 22 is new. Support for all claim amendments and the new claim can be found in the application and claims as filed. Support for amendments to Claims 1, 12, 22 can be found in paragraphs [0184] to [0185], and [0262] to [0266], at least. Support for amendments to Claim 2 can be found throughout the specification as filed, for example paragraph [0014], and [0183], at least. Claims 1-22 are pending with the entry of the above- noted claims. Reconsideration is respectfully requested in light of the following remarks.

Provisional Double Patenting

Claims 1 and 3-11 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-4 and 6-14 of co-pending U.S. Application No. 12/237,328. Claims 12-16 and 18-21 were also provisionally rejected as being unpatentable over claims 26-33 of co-pending U.S. Application No. 12/237,319. While Applicants do not necessarily agree with the position taken by the Examiner, Applicants request that such provisional rejection be held in abeyance and Applicants will consider submitting a terminal disclaimer or additional arguments at the appropriate time.

Claim Rejections - 35 USC § 101

Claim 21 was rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter. Applicants thank the examiner for the suggestion regarding the amendment that would be appropriate to overcome this rejection. Applicants have amended Claim 21 in accordance with this suggestion.

Claim Rejections – 35 USC § 102

Claims 1-5 were rejected under 35 U.S.C. 102(b) as being anticipated by USPN 6,488,617 (Katz). Applicants traverse, for at least the reasons stated below.

Katz fails to anticipate the elements of Claims 1 and 2, at least. Katz describes a feedback system, which in real time, tries to move a subject from a current brain state into a desired brain state via magnetic stimulation. Brain states targeted in Katz are categorized based

on the level of alertness of the subject. (Col. 1, line 14 to 34). These states include sleep states associated with brain wave frequencies in the delta and theta ranges of 1.5 to 3.5 Hz and 3.5 to 7 Hz, respectively, a relaxed state associated with brain wave frequencies in the alpha range of 7.5 to 12.5 Hz, and an excited state associated with brain wave frequencies in the beta range of 12.5 to 20 Hz (*Id.*, *See also*, Col. 6, lines 16-35). Thus, each state of Katz is within a different EEG band, and Katz tries to move the subject from one state (in one band) to another state (in another band). At least the following distinctions can be made from the present claims.

With respect to Claim 1, Katz fails to teach or suggest “adjusting output of a magnetic field to a setting that is operable to ...influence an intrinsic frequency of a specified EEG band of the subject toward a target intrinsic frequency of the specified EEG band.”

In contrast, Katz targets a desired brain state, which encompasses a range of frequencies in multiple bands. Claim 1 of the present invention provides for adjusting a magnetic field output to a setting operable to influence an intrinsic frequency of a specified EEG band of the subject toward a target intrinsic frequency, not toward a state encompassing a range of frequencies. The Office Action tacitly acknowledges this difference by referring to the desired state of Katz and frequencies in each state, as opposed to a particular target frequency as is claimed.

Further, Claim 1 of the present invention recites adjusting output of a magnetic field to influence the subject’s intrinsic frequency in a specified EEG band toward a target intrinsic frequency of the same EEG band. On the other hand, Katz’s only intention and goal is to move a subject from a current brain state into a desired brain state. Since the brain states correlate to separate EEG bands in Katz (i.e. from relaxed in the alpha band to sleep in the delta or theta band), Katz’ methods and devices move the brain waves from one band to another.

Also with respect to Claim 1, since Katz is concerned with moving the current brain state to another brain state, Katz fails to teach or suggest “adjusting output of a magnetic field to a setting that is operable to...influence a Q-factor of the intrinsic frequency toward a target Q-factor.” As described and shown in the instant specification (for example at paragraphs [0313], and in Figure 12, at least), a Q-factor is a measure of the distribution around the frequency within a single EEG band.

The Office Action points to Katz Column 6 lines 16-61 and states “Katz states that a higher magnitude magnetic field increases the focus of a mean frequency, which is the equivalent of modifying the bandwidth of an intrinsic frequency to a preselected bandwidth.” On the contrary,

Katz's reference to focus refers to the focal area of the brain, and not a focus of a mean frequency. Katz actually says that "a key component [of the magnetic field] is field strength. Greater magnitude [of field strength] implies more influence on the intended [focal area of the brain], although the size of that [focal area] will also increase as the magnitude [of field strength] increases" in Column 6 lines 16-61. This makes sense, since Katz uses multiple magnets having unique and varying frequencies, magnitudes, positions and durations applied to the subject's head. Thus, Katz recognizes that field strength is one parameter (of several) that may be used in order to achieve its goal of moving a subject from a state in one EEG band to a state in another EEG band; however, Katz neither discloses nor suggests "adjusting output of a magnetic field for influencing a Q-factor of an intrinsic frequency within a specified EEG band of the subject toward a pre-selected Q-factor."

Further with respect to Claim 1, as amended, Katz fails to teach or suggest "adjusting output of a magnetic field to a setting that is operable to ...influence a coherence value of intrinsic frequencies among multiple sites in a brain of the subject within a specified EEG band toward a target coherence value wherein if the coherence value is higher than the target coherence value, applying at least two asynchronous magnetic fields close to the head of the subject, and wherein if the coherence value is lower than the target coherence value, applying at least one synchronized magnetic field close to a head of the subject."

The Examiner refers to a definition of "coherence" in the Office Action based on Katz. However, Applicants respectfully disagree with this characterization of the term based on the way the term is used in the claims and specification herein. Coherence, as used in the present application, refers to how closely matched are the intrinsic frequencies among multiple sites in a brain of the subject within a specified EEG band (*e.g.*, how closely matched is a first intrinsic frequency of a first site in the brain of the subject within a specified EEG band to a second intrinsic frequency of a second site in the brain of the subject within the same EEG band, at least). (See, *e.g.* para [0169], at least). It is expressed as a coherence value. Thus, if the two or more intrinsic frequencies are matched in frequency, a coherence value shows this matching characteristic. Likewise, if the two or more intrinsic frequencies are not matched, the coherence value expresses this. A coherence value that is higher (more coherent) would indicate that the intrinsic frequencies are more closely matched than the situation in which a coherence value is lower (indicating less coherent). Accordingly, the method is written such that the subject's own coherence value may shifted up or down-- toward a pre-selected coherence value.

Katz fails to disclose or suggest this method, or a device adapted to achieve this. First, Katz fails to disclose or suggest providing a pre-selected coherence value. Second, Katz also fails to disclose or suggest determining a coherence value of the intrinsic frequencies among multiple sites in a brain of the subject within a specified EEG band. Third, Katz fails to disclose or suggest adjusting output of a magnetic field to a setting that is operable to ...influence a coherence value of intrinsic frequencies among multiple sites in a brain of the subject within a specified EEG band toward a target coherence value wherein if the coherence value is higher than the target coherence value, applying at least two asynchronous magnetic fields close to the head of the subject, and wherein if the coherence value is lower than the target coherence value, applying at least one synchronized magnetic field close to a head of the subject. Rather, Katz expresses a goal of achieving **symmetry in magnitude** of the EEG readings starting with asynchronous magnetic fields (0.5Hz, 5Hz). (See, Column 8 line 39-60, at least). Thus, any **secondary** preference toward coherent waves appears to use **asynchronous magnetic fields** to achieve coherent waves. (See, Column 8 line 39-60, at least). This is different with respect to how fields are used in Claim 1 to influence coherence toward the pre-selected coherence value.

Further, other examples in Katz (e.g. Column 8 lines 60- Column 9 line 16), again refer to the use of the methods and devices of Katz using synchronization “causing the mind to move [from a relaxed state] to a state of alert readiness.” In Katz, this is achieved with “a larger magnet set,” however, it is undisclosed in Katz how synchronization is achieved, i.e., what field distribution would achieve this. (Id.) In fact, Katz is a feedback system that adjusts based on a subject’s reaction to a particular field, and Katz indicates this “will vary from patient to patient.” Thus, Katz again fails to disclose the method of Claim 1, which describes a particular method and field arrangement to use based on the subject’s coherence value and the target coherence value, neither of which Katz discloses or suggests.

For similar reasons as noted with regard to coherence as noted above, Katz simply fails to disclose or suggest other elements of Claim 1, including “adjusting output of a magnetic field to a setting that is operable to ...influence an EEG phase between two sites in the brain of a subject of a specified EEG frequency toward a target EEG phase of the specified EEG frequency wherein the magnetic field comprises one or more magnetic field generators that are of the same frequency and are in-phase with each other, of the same frequency and out of phase with each other, or a combination thereof.”

Likewise, for similar reasons as noted with regard to Claims 1, Katz simply fails to disclose or suggest all of the elements of Claim 2. In particular, Katz fails to disclose or suggest “adjusting an intrinsic frequency of a brain of the subject within a specified EEG band by applying a magnetic field close to a head of the subject, wherein the magnetic field comprises at least one of (a) a single target frequency within the specified EEG band; (b) a plurality of frequencies within the specified EEG band; and (c) the intrinsic frequency of a brain of the subject within the specified EEG band”

Again, Katz targets a desired brain state, which encompasses a range of frequencies in multiple bands. Claim 2 of the present invention provides for applying a magnetic field output that adjusts an intrinsic frequency of a specified EEG band of the subject by applying one or more of: a single target frequency in the same EEG band as the intrinsic frequency, a plurality of frequencies within the same EEG band as the intrinsic frequency, and the intrinsic frequency of a brain of the subject within the same EEG band as the intrinsic frequency. As Katz attempts to move the subject outside of a measured state into another state, this is necessarily targeting moving the brain waves from one band to another. Thus, there is no disclosure or suggestion in Katz of a particular specific method that would achieve this which uses the same method as described and enabled in the present claim.

Based on the above, at least, Applicants submit the independent Claims 1 and 2, as amended, and all claims dependent therefrom, are in condition for allowance and advancement to allowance is earnestly solicited.

Claim Rejections - 35 USC § 103

Claim 6 was rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 6,488,617 (Katz) as applied to claim 1 above, and further in view of USPN 6,001,055 (Souder). Claims 7 and 8 were rejected under 35 U.S.C. 103(a) as being unpatentable over Katz and Souder as applied to claim 6 above and further in view of USPN 5,667,469 (Zhang). Claims 9 and 10 were rejected under 35 U.S.C. 103(a) as being unpatentable over Katz as applied to claim 1 above, and further in view of USPN 5,788,624 (Lu). Claim 11 was rejected under 35 U.S.C. 103(a) as being unpatentable over Katz as applied to claim 1 above, and further in view of USPN 3,821,949 (Hartzell).

To establish a *prima facie* case of obviousness, the cited art itself or “the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]” at the time of the

invention are to have taught or suggested the claim elements. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1742 (2007); *See also* MPEP § 2143.03. Thus, the Examiner must make “a searching comparison of the claimed invention – including all its limitations – with the teaching of the prior art.” *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995). As such, “obviousness requires a suggestion of all limitations in a claim.” *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)).

As noted above with regard to Claims 1 and 2, Katz fails to disclose or suggest all of the elements in each of the noted independent claims. None of Souder, Zhang, Lu, and Hatzell, whether considered alone or in any combination with Katz or any other reference make up for the deficiencies of Katz, as noted above. Thus, Applicants submit that independent Claims 1, and 2, and all claims dependent therefrom, are in condition of allowance. Advancement to allowance is earnestly solicited for all of Claims 1 to 11.

Claims 12-21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Souder in view of Katz. As suggested in the Office Action, Souder fails to disclose or suggest a device comprising “a means for applying a magnetic field to a head of a subject; whereby the means for applying the magnetic field is configured to influence at least one of: (a) an intrinsic frequency of a brain of the subject within a specified EEG band; (b) a Q-factor of an intrinsic frequency of the brain of the subject within a specified EEG band; (c) a coherence value of intrinsic frequencies among multiple sites in a the brain of the subject within a specified EEG band wherein if the coherence value is higher than a pre-selected coherence value, applying at least two asynchronous magnetic fields close to the head of the subject, and wherein if the coherence value is lower than the pre-selected coherence value, applying at least one synchronized magnetic field close to a head of the subject; and (d) a EEG phase between two sites in the brain of the subject of a specified EEG frequency wherein the magnetic field comprises a first magnetic field that is in-phase with a second magnetic field or a first magnetic field that is out of phase with a second magnetic field.” For similar reasons as noted with regard to Claim 1, above, Katz fails to make up for the deficiencies of Souder. Whether considered alone or in combination, both Souder and Katz fail to disclose or suggest all of the elements of Claim 12.

As noted above, Katz moves a subject **from a current brain state into a desired brain state**. Since the brain states correlate to separate EEG bands in Katz (i.e. from relaxed in the

alpha band to sleep in the delta or theta band), Katz' methods and devices move the brain waves from one band to another. This fails to disclose or suggest a device configured to influence a subject's intrinsic frequency within **a specified EEG band**.

Further, Katz fails to disclose or suggest a device that is configured to influence a Q-factor. The sections of Katz referred to in the Office Action misconstrue the word "focus" to mean a distribution around a frequency. On the contrary, Katz uses the term "focus" to refer to the "focal area of the brain." This is supported by Katz and technically justified based on Katz itself, at least, since when an increased magnitude of field strength is applied to a location on the brain of a subject, the focal area of the field brain likewise increases (i.e., the field reaches farther, wider into the brain of the subject). Thus, Katz fails to provide or suggest a device configured to influence a Q-factor.

Likewise, Katz fails to provide or suggest a device configured influence a subject's coherence value to lower or raise the coherence value as claimed, since Katz expresses a goal of achieving **symmetry in magnitude** of the EEG readings starting with asynchronous magnetic fields (0.5Hz, 5Hz). Thus, any **secondary** preference toward coherent waves appears to also use **asynchronous magnetic fields**. (See, Column 8 line 39-60, at least). This is different with respect to how fields are configured in Claim 12 to influence the subject's coherence value toward the pre-selected coherence value.

Furthermore, Katz fails to provide or suggest a device configured to influence an EEG phase between two sites in the brain of the subject of a specified EEG frequency wherein the magnetic field comprises a first magnetic field that is in-phase with a second magnetic field or a first magnetic field that is out of phase with a second magnetic field for similar reasons as noted above, at least.

In sum, since neither Souder nor Katz disclose or suggest all of the elements of Claim 12, this claim is in condition of allowance. So to, therefore, are all claims dependent from Claim 12 in condition of allowance. Advancement to allowance is earnestly solicited for all of Claims 12 to 21.

Attorney Docket No. 35784-706.201
(formerly: 35784-701.202)

CONCLUSION

In light of the remarks set forth above, Applicants believe that the pending claims are under condition for allowance. Applicants respectfully solicit the Examiner to expedite the prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned.

The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit account No. 23-2415 (Attorney Docket No. 32695-706.201).

Respectfully submitted,

Date: March 12, 2012

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EXAMINER

LANNU, JOSHUA DARYL DEANON

ART UNIT	PAPER NUMBER
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3735

MAIL DATE	DELIVERY MODE
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05/21/2012

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<i>Applicant-Initiated Interview Summary</i>	Application No. 12/850,547	Applicant(s) PHILLIPS ET AL.	
	Examiner JOSHUA D. LANNU	Art Unit 3735	

All participants (applicant, applicant's representative, PTO personnel):

(1) JOSHUA D. LANNU. (3) KRISTIN HAVRANEK , MATTHEW V. GRUMLING.

(2) CHARLES A. MARMOR. (4) JAMES PHILIPS and JOHN CARNUCIO .

Date of Interview: 14 May 2012.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☒102 ☐103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: 1.

Identification of prior art discussed: US 6488617 (Katz).

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Applicants, Applicant's representative, and Examiners discussed and clarified the terms of intrinsic frequency, Q-factor and coherence. No agreement was reached regarding claim 1. Prior art and double patenting issues with family related cases were discussed and terminal disclaimers or arguments will be submitted at a later time.

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/J. D. L./ Examiner, Art Unit 3735	/Charles A. Marmor, II/ Supervisory Patent Examiner, Art Unit 3735
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Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/850,547	08/04/2010	James William Phillips	35784-706.201	1056

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 WILSON, SONSINI, GOODRICH & ROSATI
 650 PAGE MILL ROAD
 PALO ALTO, CA 94304-1050

EXAMINER

LANNU, JOSHUA DARYL DEANON

ART UNIT	PAPER NUMBER
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3735

MAIL DATE	DELIVERY MODE
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07/19/2012

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

12/850,547

Applicant(s)

PHILLIPS ET AL.

Examiner

JOSHUA D. LANNU

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2012 and 12 March 2012.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-22 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☒ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-22 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/6/2012</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

This action is in response to the communication received on 3/12/2012 and the interview on 5/14/2012. Examiner acknowledges amendments made to claims 1, 3, 4, 6-9, 12-16, and 25 and the addition of claim 26. Examiner thanks the Applicants and their council for the clarifications of certain terms.

Double Patenting

Claims 1 and 3-11 of this application conflict with claims 1-4 and 6-14 of Application No. 12237328. Claims 12-16 and 18-21 of this application conflict with claims 26-33 of Application No. 12237319. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference

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claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 3-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 6-14 of copending Application No. 12237328. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application discloses the same method for treating depression, which is associated with Post Traumatic Stress Disorder (PTSD). Because depression is associated with PTSD, the method proposed in the copending application anticipates the method's use in treating a subject for PTSD.

Claims 12-16 and 18-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-33 of copending

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Application No. 12,237,319. Although the conflicting claims are not identical, they are not patentably distinct from each other because the device specified in claims 26-33 of the copending application are more specific and anticipate the more general form of the device, which is proposed in claims 16-20 and 22-25 of the current application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 2-5 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by US

6,488,617 (Katz).

3. **In regards to claim 2**, Katz discloses a method for treating depression, which is associated with PTSD. Katz discloses the step of applying a magnetic field close to the head of a subject (figure 2) to induce a desired frequency which is correlated to a particular brain state (column 6 lines 16-61). Katz further states inducing states of relaxation, which in essence is adjusting the intrinsic frequency of a subject within a specified EEG band (the actual frequency) towards a desired frequency to induce the specific brain state by the application of a magnetic field (column 8, line 60 – column 9, line 16). Katz further states that the magnetic field will pulse at a unique frequency for each magnet to excite or suppress cortical activity (column 6, lines 40-

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44). In the magnetic field would have to have at least one of (a) a single target frequency within the specified EEG band; (b) a plurality of frequencies within the specified EEG band; and (c) the intrinsic frequency of a brain of the subject within the specified EEG band. Furthermore, an adjustment to the intrinsic frequency would naturally influence the Q-factor of the intrinsic frequency, although in what direction is unknown.

4. **In regards to claims 3-5**, Katz discloses all elements of claim 2. In addition, Katz states the step of measuring EEG data after the application of the magnetic field in claim 21. Katz discloses the step of adjusting parameters of the magnetic field and repeating the applying step with an adjusted parameter in claim 21. Katz further states that pulse frequency of the magnetic field is one of the parameters (column 6, lines 45-54). Katz also teaches the application of a larger magnet set to achieve large scale synchronization of two hemispheres (column 8, line 39 – column 9, line 16), which is interpreted as the application of a magnetic field over a diffuse area of the brain. Katz also states that frequencies between 1.5 Hz and 7.5 Hz induce a specific type of intrinsic frequency band (column 6, lines 29-34) and further states that frequencies below 1 Hz suppress activity while frequencies about 1 Hz excite the cortex.

5. **In regards to claim 22**, Katz discloses an embodiment where the device is comprised of a Transcranial Magnetic Stimulation (TMS) device. Figure 2 shows a TMS device setup where one hemisphere at a time is stimulated and is located on the head of a subject (column 8, lines 28-59). The TMS device would then be a means for applying a magnetic field to a head of a subject, a magnetic field generator. Because the application of a magnetic field would naturally influence intrinsic frequencies in EEG bands or a Q-factor of an intrinsic frequency, the device is configured to influence an intrinsic frequency of a brain of a subject within a specified EEG band

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or a Q-factor of an intrinsic frequency of the brain of a subject within a specified EEG band.

Katz as applied to claims 1 and 2 discloses the steps of using the device to influence an intrinsic frequency of a brain of the subject within a specified EEG band or a Q-factor of an intrinsic frequency of a brain subject within a specified EEG band. Figure 1 discloses the system and shows EEG electrodes (element 1) with an EEG preprocessing circuit (elements 5 and 6), and a computation system (element 7) which would be the EEG device. Katz also discloses that the EEG device relays information to the TMS device in order to achieve coherence (column 8, lines 39-59). In addition, Katz also states that the TMS device (elements 7 and 8) adjusts stimulation based on received information from the EEG device and the data is used in order to achieve coherence or influencing a specific intrinsic frequency (column 6, line 62- column 7, line 18; column 8, lines 39-59). This adjustment is done by a computational system (figure 1, element 7; abstract; column 6, lines 16-35). Because there is a computer involved (see claim 2), a processing unit (processor) is present to control repetitive firing of the magnetic field based in an intrinsic frequency of a subject within a specified EEG band. Furthermore the limitation “wherein the magnetic field ...EEG band” is a statement of intended use/result which does not make the claim different from prior art unless it results in a clear structural difference.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,488,617 (Katz) as applied to claim 2 above, and further in view of US 6,001,055 (Souder).

9. **In regards to claim 6**, Katz discloses all limitations of claims 2. However Katz does not use a permanent magnet to generate the magnetic field for magnetic therapy in the mentioned method. Souder discloses the use of a magnetic therapy device with at least one permanent magnet (element 24; column 2, lines 58-63). Souder states that a moving magnetic field is generated by the rotation of the permanent magnet and subjects the treatment area to varying intensities of north or south pole fields (column 6, lines 1-36). In addition Souder states that applying the dynamic field enhances the beneficial effects of magnetic therapy (column 1, lines 25-30). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a permanent magnet with rotational motion as taught by Souder in the method of Katz in order to enhance the beneficial effects of magnetic therapy.

10. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,488,617 (Katz) and US 6,001,055 (Souder) as applied to claim 6 above, and further in view of US 5,667,469 (Zhang et al.).

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11. **In regards to claims 7 and 8**, Katz and Souder disclose the limitations of claim 6.

However, Katz and Souder do not explicitly state that the strength of the permanent magnet is from about 10 Gauss to about 4 Tesla nor state that the distance between the permanent magnet and the subject is from about 1/32 inch to about 12 inches. Zhang et al. (hereinafter referred to as Zhang) teaches a rotating permanent magnet device for medical therapy. Zhang states that the magnet of the device can generate a magnetic field intensity of about 0.1-0.8 Tesla (column 6, lines 6-24), which falls within the range specified in claim 7. Katz states that increasing the magnitude of the magnetic field implies a greater focus (column 6, lines 40-44). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the permanent magnet with a strength of about 0.1-0.8 Tesla as taught by Zhang in the method disclosed by Katz and Souder in order to increase focus of a magnetic field in a treatment area.

12. Katz, Souder and Zhang do not address the specific distance of the patient and the magnet. It can be seen in figure 3 of Zhang that the patient is placed on a table with the magnet underneath the table exerting its magnetic field. Zhang states that the treatment diameter can go up to 950 mm/37.4 inches (column 6, lines 6-24). The treatment radius then would be 19.7 inches, where the treatment radius is interpreted as range of distances from the magnet where a patient can be placed. Zhang does not address the range specified. However the treatment diameter of 37.4 inches includes the specified range of 1/32 inch to 12 inches. Applicant has not disclosed that the range specified solves any stated problem or is for any particular purpose. Moreover, it appears that the range used by Katz, Souder, and Zhang or the applicant's invention would perform equally well with applying the magnetic field to the head to influence EEG signals from an actual to a desired state.

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13. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified Katz, Souder, and Zhang such that the range used between the subject and magnet in the method is from about 1/32 inch to about 12 inches because the general conditions of the claim are disclosed in the prior art. Furthermore, it would be the natural desire of scientists or artisans to optimize ranges in order to improve on what is generally known.

14. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over 6,488,617 (Katz) as applied to claim 2 above, and further in view of US 5,788,624 (Lu et al.).

15. **In regards to claims 9 and 10**, Katz discloses the limitations of claim 2. However, Katz makes no mention of the timing of application of the magnetic field. Lu et al. (hereinafter referred to as Lu) discloses a step of administering magnetic field therapy with a duration of 20-40 minutes once each a day for a period of 12 -14 days (column 3, lines 55-64). Lu states that a transient magnetic field does not make a patient uncomfortable and that exposure to a continuous magnetic field may cause other issues such as headaches, insomnia, etc... (column 3, line 65 – column 4 line 14). Lu also states that transient application brings an effective interaction of the blood, body fluids, nervous system, channels, and collaterals of the body within a short period of time (column 2, lines 33-41). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use transient magnetic fields with durations of 20-40 minutes per day over 12-14 days as taught by Lu in the method of Katz in order to provide an effective interaction of blood, body fluids, nervous system, channels, and collaterals of the body.

16. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over 6,488,617 (Katz) as applied to claim 2 above, and further in view of US 3,821,949 (Hartzell et al.).

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17. **In regards to claim 11**, Katz discloses the limitations of claims 2. Katz teaches the use of a device with magnetic stimulation and EEG recording capabilities to produce a desired brain state. In figure 1 a set of electrodes (element 1) are located on the scalp of the subject to measure the EEG, brain activity, of the individual (column 5, lines 20-33). Electrical resistivity is the measure of how strongly a material opposes the flow of electric current. Because all the electrodes are on skin, which allows electric current to flow, the electrodes would be on an area of low electrical resistivity. Electrical impulse interference is essentially noise. Additionally, because the electrodes are on the scalp, the electrodes are in an area with substantially no electrical impulse interference due to the electrical signals being mostly coming from neurons instead of other sources such as eye muscles. All the electrodes are operable to detect brain activity. If one electrode is chosen as the one for detecting brain activity, any of the other electrodes can function as a second electrode that is operable to detect a reference signal. Katz also states the step of determining the mean frequency, an intrinsic frequency, of a subject in order to determine differences between an actual and desired brain state (column 6, lines 16-61). However, Katz does not explicitly state that the intrinsic frequency is determined from the electrical activity from the first electrode and the reference signal detected by the second electrode. Hartzell discloses the specifics of EEG devices. Hartzell specifically outlines the use of a reference electrode (element 38) and an active electrode (element 46) to sense brain wave potentials (column 7, line 55 – column 8, line 14). The biofeedback apparatus (figure 2, element 10a) takes the signals from the active electrode and the reference electrode. The signal is then run through amplifiers and passed through filters for specific frequency ranges to determine the frequencies for alpha, beta, and theta bands (column 8, line 15 – column 9, line 2). Hartzell in

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particular specifies using the ear lobes as reference and neutral electrodes to sense brain wave potentials (column 8, lines 2-14) It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a reference and source electrode as taught by Hartzell in the method disclosed by Katz in order to detect and sense the brain wave potentials.

18. Claims 12-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,001,055 (Souder) and in view of US 6,488,617 (Katz).

19. **In regards to claims 12-17**, Souder discloses a device that is used for magnetic therapy. The device extends a magnetic field for application to an anatomical area (see abstract). Souder discloses several device embodiments made of at least one permanent magnet (element 24, column 6, lines 14-16) and a subunit coupled to the magnet that allows the magnet to rotate in a rotational motion (column 6, lines 37-39) such as element 20 in figure 3. Souder states that a moving magnetic field is generated by the rotation of the permanent magnet and subjects the treatment area to varying intensities of north or south pole fields (column 6, lines 1-36). Souder also states that the user is subjected to alternating magnetic fields (column 10, lines 9-15). Souder mentions the concept of making an alternating magnetic field as moving magnets relative to a treatment area (column 5, lines 58-61). Souder also states that the speeds at which the shafts spin the magnets are preferably between 400 – 8000 revolutions per minute (RPMs), which based on RPM to Hz conversions would be between 6.66 Hz and 133.33 Hz (column 8, lines 17-32) which overlaps in the range specified by Applicant. However, Souder does not explicitly disclose that the device is configured to influence an intrinsic frequency of a brain of the subject within a specified EEG band, a Q-factor if an intrinsic frequency of a brain of the subject within a specified EEG band, a coherence of intrinsic frequencies among multiple sites in a brain of a

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subject of a specified EEG band, and a phase between two sites in the brain of a subject of a specified EEG frequency. Katz teaches a magnetic therapy device that can be used for treating depression (claim 15). The device of Katz implements a method that uses magnetic fields, as applied to claim 2 of the current application, to influences an intrinsic frequency of a brain of the subject within a specified EEG band, which makes it configured to influence at least one of the disclosed parameters. Katz further states that being able to influence these EEG frequencies allows improvement of deficient or non-optimal mental states (column 1, lines 57-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a the capability of influencing an intrinsic frequency of a brain of the subject within a specified EEG band, a Q-factor if an intrinsic frequency of a brain of the subject within a specified EEG band, a coherence of intrinsic frequencies among multiple sites in a brain of a subject of a specified EEG band, and a phase between two sites in the brain of a subject of a specified EEG frequency as taught by Katz in the device of Souder in order to improve deficient or non-optimal mental states.

20. **In regards to claims 18**, Souder and Katz disclose the limitations of claim 12. Souder also states that the speeds at which the shafts spin the magnets are preferably between 400 – 8000 revolutions per minute (RPMs), which based on RPM to Hz conversions would be between 6.66 Hz and 133.33 Hz (column 8, lines 17-32) which. In addition, Souder states that the device is capable of going to lower frequencies as dictated to get to an optimal frequency (column 8, lines 30-32), which would enable movement to the at the 0.5 Hz frequency. However, Souder does not explicitly state that the device further comprises a logic that controls the frequencies in increments of about 0.1 Hz. Katz teaches the logic (element 7) that controls frequency

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stimulation. Because the logic is depicted as a computer, it would be capable of controlling frequencies by increments of 0.1 Hz. Katz includes this feature in his system to influence these EEG frequencies and allow improvement of deficient or non-optimal mental states (column 1, lines 57-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a logic to control frequency as taught by Katz into the device disclosed by Souder in order to influence EEG frequencies and allow improvement of deficient and non-optimal mental states.

21. **In regards to claims 19 and 20**, Souder and Katz disclose all limitations of claim 12, but do not explicitly state that the device is operable to influence or calculate at least one of the following: an intrinsic frequency of the brain of the subject within a specified EEG band; a Q-factor of the at least one intrinsic frequency, coherence values of intrinsic frequencies from multiple sites in the brain of a subject within a specified EEG band; and an EEG phase between two sites in the brain of a subject of a specified EEG frequency. Souder also does not disclose logic that changes the frequency of magnet movement in response to EEG readings of a subject during treatment. Katz discloses a device that influences the intrinsic frequencies of the brain of a subject (column 6, lines 16-35), influence a Q factor of the intrinsic frequency (column 6 lines 16-35), influence coherence of intrinsic frequencies among multiple sites in the brain of a subject within a specified EEG band (column 8, lines 39-59), and influence an EEG phase between two sites in the brain of a subject (column 8, lines 39-59). In addition Katz teaches a logic device (element 7) that automatically changes frequencies in response to an EEG signal (column 6, line 62- column 8, line 5) and calculates intrinsic frequency data, Q-factors of intrinsic frequency, coherence values of intrinsic frequencies and EEG phase from collected EEG data (column 6,

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lines 16-35). Katz further states that being able to influence these EEG frequencies allows improvement of deficient or non-optimal mental states (column 1, lines 57-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a logic that changes magnetic stimulation frequencies and calculate EEG information and influence EEG data as taught by Katz in the device of Souder in order to improve deficient or non-optimal mental states.

22. **In regards to claim 21**, Souder and Katz disclose all limitations of claim 12. In addition, Katz teaches a device with magnetic stimulation and EEG recording capabilities to produce a desired brain state. In figure 1 a set of electrodes (element 1) are placed on the scalp of the subject to measure the EEG, brain activity, of the individual (column 5, lines 20-33). All the electrodes are operable to detect brain activity. If one electrode is chosen as the one for detecting brain activity, any of the other electrodes can function as a second electrode to detect a reference signal. Katz shows EEG comparisons to determine coherence between the left and right hemispheres (column 8, lines 39-59), which in essence is a difference or correlation between a signal and a reference signal. Electrical resistivity is the measure of how strongly a material opposes the flow of electric current. Because all the electrodes are on skin, which allows electric current to flow, the electrodes would be on an area of low electrical resistivity. Electrical impulse interference is essentially noise. Because the electrodes are on the scalp, the electrodes are in an area with substantially no electrical impulse interference due to the electrical signals being mostly coming from neurons instead of other sources such as eye muscles. Katz states that having feedback with the therapy allows for the minimization of differences between an actual and desired brain state (see abstract). It would have been obvious to one of ordinary skill in the

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art at the time the invention was made to incorporate the measurement of EEG signals as taught by Katz with the magnetic device of Souder in order to determine if the therapy is inducing a desired brain state.

Response to Arguments

1. Examiners thank Applicant and Applicant's counsel for the clarification of terms and explanation of the inventive concept.
2. Applicant's arguments filed 3/12/2012 have been fully considered but they are not persuasive.
3. In regards to claim 2, Applicant states that Katz fails to teach the limitations of claim 2 due to Katz shifting the brain waves from one band to another. Examiner respectfully disagrees. Katz does adjust an intrinsic frequency of a brain of the subject within a specified EEG band by applying a magnetic field close to the subject because Katz finds the intrinsic frequency of a band before it is shifted to another band to modulate the brain state. As stated in the rejection above the magnetic field would have to have at least one of the parameters specified.
4. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., adjustment of the intrinsic frequency from the current frequency to a target frequency within the same EEG band) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

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5. In regards to claims 12, Applicant argues that the combination of Souter and Katz fails to disclose or suggest the elements as claimed because Katz does not disclose the elements of claim 1 and 2. Examiner respectfully disagrees. As noted in the rejection above, Katz discloses the methods of claim 2 with a device with that is configured to influence at least one of the claimed parameters. In this case it the intrinsic frequency of a brain of a subject within a specified EEG band.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSHUA D. LANNU whose telephone number is (571)270-1986. The examiner can normally be reached on Monday-Friday 8:00-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles A. Marmor can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. D. L./
Examiner, Art Unit 3735

/John P Lacyk/
Primary Examiner, Art Unit 3735

ELECTRONICALLY FILED ON SEPTEMBER 10, 2012

**Attorney Docket No. 35784-706.201
PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: James William Phillips et al.

Serial Number: 12/850,547

Filing Date: August 4, 2010

Title: SYSTEMS AND METHODS FOR
MODULATING THE ELECTRICAL
ACTIVITY OF A BRAIN USING NEURO-
EEG SYNCHRONIZATION THERAPY

Group Art Unit: 3735

Examiner: Lannu, Joshua Daryl Deanon

Confirmation No: 1056

Customer No. 021971

AMENDMENT IN RESPONSE TO FINAL OFFICE ACTION

MAIL STOP AF
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Commissioner:

This paper responds to the Final Office Action dated July 19, 2012 setting an initial due date of October 19, 2012, with a two month Advisory Action deadline of September 19, 2012. Therefore, Applicants believe that this response is being timely filed. Applicants believe no fees are due with this submission.

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 7 of this paper.

Conclusion begins on page 11 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings of claims in this application. Applicant reserves the right to pursue any subject matter of any canceled claims in this or any other appropriate patent application. Support for these claims is provided in the remarks following the listing of claims.

1. (Previously Presented) A method of treating Parkinson's disease, treating coma, treating post traumatic stress disorder (PTSD), treating amblyopia, and/or enhancing cognitive performance, in a subject, comprising:
 - (a) adjusting output of a magnetic field to a setting that is operable to do one or more of the following:
 - (1) influence an intrinsic frequency of a specified EEG band of the subject toward a target intrinsic frequency of the specified EEG band,
 - (2) influence a Q-factor of the intrinsic frequency toward a target Q-factor,
 - (3) influence a coherence value of intrinsic frequencies among multiple sites in a brain of the subject within a specified EEG band toward a target coherence value wherein if the coherence value is higher than the target coherence value, applying at least two asynchronous magnetic fields close to the head of the subject, and wherein if the coherence value is lower than the target coherence value, applying at least one synchronized magnetic field close to a head of the subject; and
 - (4) influence an EEG phase between two sites in the brain of a subject of a specified EEG frequency toward a target EEG phase of the specified EEG frequency wherein the magnetic field comprises one or more magnetic field generators that are of the same frequency and are in-phase with each other, of the same frequency and out of phase with each other, or a combination thereof; and
 - (b) applying said magnetic field close to a head of the subject.

2. (Currently Amended) A method of treating Parkinson's disease, treating coma, treating post traumatic stress disorder (PTSD), treating amblyopia, and/or enhancing cognitive performance in a subject, comprising ~~adjusting~~ influencing at least one of:
 - an intrinsic frequency of a brain of the subject within a specified EEG band toward a pre-selected intrinsic frequency within the same specified EEG band and
 - a Q-factor of the intrinsic frequency within the same specified EEG band,
 by applying a magnetic field close to a head of the subject, wherein the magnetic field comprises at least one of (a) a single target frequency within the specified EEG band; (b) a plurality of frequencies within the specified EEG band; and (c) the intrinsic frequency of a brain of the subject within the specified EEG band ~~wherein adjusting the intrinsic frequency comprises~~ influencing a Q-factor of the intrinsic frequency.
3. (Original) The method of claim 1 or 2, further comprising the step of measuring EEG data of the subject after the applying step.
4. (Original) The method of claim 1 or 2, further comprising the steps of: adjusting frequency of said magnetic field based on the EEG data of the subject; and repeating the applying step with an adjusted frequency.
5. (Original) The method of claim 1 or 2, wherein the applying of the magnetic field applies the magnetic field to a diffuse area in a brain of the subject.
6. (Original) The method of claim 1 or 2, wherein the magnetic field is generated by movement of at least one permanent magnet.
7. (Original) The method of claim 6, wherein the strength of the at least one permanent magnet is from about 10 Gauss to about 4 Tesla.
8. (Original) The method of claim 7, wherein the distance between the at least one permanent magnet and the subject is from about 1/32 in to about 12 in.
9. (Original) The method of claim 1 or 2, wherein the step of applying the magnetic field is for about 5 minutes to about two hours.

10. (Original) The method of claim 1 or 2, further comprising repeating the applying step after an interval about 6 hours to about 14 days.
11. (Original) The method of claim 1 or 2, further comprising: (a) locating a first electrode operable to detect electrical brain activity on the subject in at least one of an area of low electrical resistivity on a subject, and an area with substantially no electrical impulse interference on a subject; (b) locating a second electrode operable to detect a reference signal on the subject; and (c) determining the intrinsic frequency from the electrical brain activity detected by the first electrode and the reference signal detected by the second electrode.
12. (Currently Amended) A device for use in treating Parkinson's disease, treating coma, treating post traumatic stress disorder (PTSD), treating amblyopia, and/or enhancing cognitive performance in a subject, comprising: a means for applying a magnetic field to a head of a subject; whereby the means for applying the magnetic field comprises a processor or logic that controls the application of the magnetic field and logic that implements the methods of Claims 1, 2, or a combination thereof ~~is configured to influence at least one of: (a) an intrinsic frequency of a brain of the subject within a specified EEG band; (b) a Q-factor of an intrinsic frequency of the brain of the subject within a specified EEG band; (c) a coherence value of intrinsic frequencies among multiple sites in the brain of the subject within a specified EEG band wherein if the coherence value is higher than a pre-selected coherence value, applying at least two asynchronous magnetic fields close to the head of the subject, and wherein if the coherence value is lower than the pre-selected coherence value, applying at least one synchronized magnetic field close to a head of the subject; and (d) a EEG phase between two sites in the brain of the subject of a specified EEG frequency wherein the magnetic field comprises a first magnetic field that is in phase with a second magnetic field or a first magnetic field that is out of phase with a second magnetic field.~~
13. (Original) The device of claim 12, comprising at least one permanent magnet.
14. (Original) The device of claim 12, wherein the magnetic field is generated by movement of at least one permanent magnet.

15. (Original) The device of claim 12, wherein the movement of the at least one said magnet is at a frequency between about 0.5 Hz and about 100 Hz.
16. (Original) The device of claim 12, wherein said movement comprises at least one of rotational motion, linear motion, and swing motion.
17. (Original) The device of claim 12, wherein said movement generates an alternating magnetic field.
18. (Original) The device of claim 12, further comprising logic that controls the frequency to be any frequency between about 0.5 Hz and about 100 Hz in increments of about 0.1 Hz.
19. (Original) The device of claim 12, further comprising logic that automatically changes the frequency in response to EEG readings of a subject during treatment.
20. (Original) The device of claim 12, further comprising logic that calculates information from EEG data collected from the subject within a specified EEG band, wherein said information comprises at least one of items listed below: (a) at least one intrinsic frequency; (b) Q-factor of the at least one intrinsic frequency; (c) a coherence value of intrinsic frequencies; (d) an EEG phase; and (e) any combination thereof.
21. (Previously Presented) The device of claim 12, further comprising: (a) a first electrode operable to detect electrical brain activity; and (b) a second electrode operable to detect a reference signal; wherein the first electrode adapted to be located on the subject in at least one of: an area of low electrical resistivity on a subject, and an area with substantially no electrical impulse interference on a subject, and wherein the second electrode adapted to be located on the subject.
22. (Currently Amended) A device for treating Parkinson's disease, treating coma, treating post traumatic stress disorder (PTSD), treating amblyopia, and/or enhancing cognitive performance in a subject, comprising a magnetic field generator configured apply a magnetic field close to a head of the subject, wherein the magnetic field generator comprises a processor or logic that controls the application of the magnetic field and logic that

~~implements the methods of Claims 1, 2, or a combination thereof, and wherein the magnetic field is chosen in order to adjust a Q-factor of an intrinsic frequency of a brain of the subject within a specified EEG band by, wherein the magnetic field comprises at least one of (a) a single target frequency within the specified EEG band; (b) a plurality of frequencies within the a specified EEG band; and (c) the intrinsic frequency of a brain of the subject within the a specified EEG band.~~

23. (New) The device of claim 22, wherein the magnetic field comprises at least one of (a) a single target frequency within the specified EEG band; (b) a plurality of frequencies within the a specified EEG band; and (c) the intrinsic frequency of a brain of the subject within the a specified EEG band.

REMARKS

The following remarks are in response to the Examiner's Final Office Action mailed on July 19, 2012. Claims 2, 12, and 22 are amended. Claim 23 is new. Support for claim amendments can be found in the application as filed, and specifically, Claim 23 support can be found in Claim 22 as originally filed. Claims 1-23 are pending. Reconsideration is respectfully requested in light of the following remarks.

Double Patenting Rejection

Claims 1 and 3-11 have been provisionally rejected as being upatentable over claims 1-4 and 6-14 of copending Application No. 12/237,328. Claims 12-16 and 18-21 have been provisionally rejected as being upatentable over claim 26-33 of copending Application No. 12/237,319. In response, Applicants herewith submit terminal disclaimers which obviate the provisional nonstatutory double patenting rejections. Withdrawal of such rejections is respectfully requested. As there are no rejections of Claim 1 other than the provisional nonstatutory double patenting rejections, Applicants submit that the terminal disclaimers filed puts this claim, at least, in condition of allowance. Thus, Applicants thank the Examiner for the indication of allowance of Claim 1.

Claim Rejections – 35 USC § 102

Claims 2-5 and 22 have been rejected under 35 U.S.C. 102 as being anticipated by US 6,488,617 ("Katz").

Katz fails to anticipate the elements of Claims 2-5 and 22, at least. Katz describes a feedback system, which in real time, tries to move a subject from a current brain state into a desired brain state via magnetic stimulation. Brain states targeted in Katz are categorized based on the level of alertness of the subject. (Col. 1, line 14 to 34). These states include sleep states associated with brain wave frequencies in the delta and theta ranges of 1.5 to 3.5 Hz and 3.5 to 7 Hz, respectively, a relaxed state associated with brain wave frequencies in the alpha range of 7.5 to 12.5 Hz, and an excited state associated with brain wave frequencies in the beta range of 12.5 to 20 Hz (*Id.*, See also, Col. 6, lines 16-35). Thus, each state of Katz is within a different

EEG band, and Katz tries to move the subject from one state (in one band) to another state (in another band). At least the following distinctions can be made from the present claims.

With respect to Claim 2, Katz fails to teach or suggest “influencing at least one of: an intrinsic frequency of a brain of the subject within a specified EEG band toward a pre-selected intrinsic frequency within the same specified EEG band and a Q-factor of the intrinsic frequency within the same specified EEG band.”

In contrast, Katz targets a desired brain state, which encompasses a range of frequencies in multiple bands. Claim 2 of the present invention targets a pre-selected intrinsic frequency, not a state encompassing a range of frequencies. The Office Action tacitly acknowledges this difference by referring to the desired state of Katz and frequencies in each state, as opposed to a particular pre-selected frequency as is claimed.

Further, Claim 2 of the present invention recites adjusting output of a magnetic field and influencing the subject’s intrinsic frequency in a specified EEG band toward a pre-selected intrinsic frequency of the same EEG band. On the other hand, Katz’s only intention and goal is to move a subject from a current brain state into a desired brain state. Since the brain states correlate to separate EEG bands in Katz (i.e. from relaxed in the alpha band to sleep in the delta or theta band), Katz’ methods and devices move the brain waves from one band to another.

Alternatively, or additionally, Claim 2 targets a Q factor of an intrinsic frequency within a single EEG band (the “specified EEG band”). As described and shown in the instant specification (for example at paragraphs [0300], [0326] and in Figure 12, at least), a Q-factor is a measure of the distribution around the frequency within a single EEG band. Changing a frequency from one band to another band does not inherently or necessarily change the Q-factor, which is essentially a distribution around a particular frequency. In contrast, Katz makes no effort or disclosure regarding the Q-factor or other distribution of frequencies around an intrinsic frequency.

The Office Action points to Katz Column 6 lines 16-61 and states “Katz states that a higher magnitude magnetic field increases the focus of a mean frequency, which is the equivalent of modifying the bandwidth of an intrinsic frequency to a preselected bandwidth.” On the contrary, Katz’s reference to focus refers to the focal area of the brain, and not a focus of a mean frequency. Katz actually says that “a key component [of the magnetic field] is field strength. Greater magnitude

[of field strength] implies more influence on the intended [focal area of the brain], although the size of that [focal area] will also increase as the magnitude [of field strength] increases” in Column 6 lines 16-61. This makes sense, since Katz uses multiple magnets having unique and varying frequencies, magnitudes, positions and durations applied to the subject’s head. Thus, Katz recognizes that field strength is one parameter (of several) that may be used in order to achieve its goal of moving a subject from a state in one EEG band to a state in another EEG band; however, Katz neither discloses nor suggests “adjusting output of a magnetic field ... and influencing a Q-factor of an intrinsic frequency within a specified EEG band of the subject toward a pre-selected Q-factor.”

Likewise, for similar reasons as noted with regard to Claims 2, Katz simply fails to disclose or suggest all of the elements of each of Claims 3-5 and 22, at least. Based on the above, at least, Applicants submit the independent Claims 1, 2 (as amended), and 22 (as amended) and all claims dependent therefrom, are in condition for allowance and advancement to allowance is earnestly solicited.

Claim Rejections - 35 USC § 103

Claim 6 has been rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,488,617 (“Katz”) as applied to claim 2, and further in view of 6,001,055 (“Souder”). Claims 7 and 8 have been rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,488,617 (“Katz”) and US 6,001,055 (“Souder”) as applied to claim 6, and further in view of US 5,667,469 (“Zhang”). Claims 9 and 10 have been rejected under 35 U.S.C. 103(a) as being unpatentable over 6,488,617 (“Katz”) as applied to claim 2, and further in view of US 5,788,624 (“Lu”). Claim 11 has been rejected under 35 U.S.C. 103(a) as being unpatentable over 6,488,617 (“Katz”) as applied to claim 2, and further in view of US 3,821,949 (“Hartzell”).

To establish a *prima facie* case of obviousness, the cited art itself or “the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]” at the time of the invention are to have taught or suggested the claim elements. *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1742 (2007); *See also* MPEP § 2143.03. Thus, the Examiner must make “a searching comparison of the claimed invention – including all its limitations – with the teaching of the prior art.” *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995). As such, “obviousness requires a

suggestion of all limitations in a claim.” *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)).

As noted above with regard to Claims 2, Katz fails to disclose or suggest all of the elements in each of the noted independent claim. None of Souder, Zhang, Lu, or Hartzell, whether considered alone or in any combination with Katz or any other reference make up for the deficiencies of Katz, as noted above. Thus, Applicants submit that independent Claim 2, and all claims dependent therefrom, are in condition of allowance. Advancement to allowance is earnestly solicited for all of Claims 1 to 11.

Claims 12-21 have been rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,001,055 (“Souder”) and in view of US 6,488,617 (“Katz”). On the contrary, Souder fails to disclose or suggest a device comprising “a means for applying a magnetic field to a head of a subject; whereby the means for applying the magnetic field comprises a processor or logic that controls the application of the magnetic field and logic that implements the methods of Claims 1, 2, or a combination thereof ” as required in Claim 12, as amended, and thus, required in any claim dependent therefrom. Katz fails to make up for the deficiencies of Souder as noted with regard to Claims 2 or 22, above. Based on this, at least, Applicants submit the independent Claim 12, as amended, and all claims dependent therefrom, are in condition for allowance and advancement to allowance is earnestly solicited.

Attorney Docket No. 35784-706.201

CONCLUSION

In light of the remarks set forth above, Applicants believe that the pending claims are under condition for allowance. Applicants respectfully solicit the Examiner to expedite the prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned.

The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 23-2415 (Attorney Docket No. 35784-706.201).

Respectfully submitted,

Date: September 10, 2012

By: /Kristin Havranek/
Kristin Havranek
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/850,547	08/04/2010	James William Phillips	35784-706.201	1056

21971 7590 01/03/2013
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PALO ALTO, CA 94304-1050

EXAMINER

LANNU, JOSHUA DARYL DEANON

ART UNIT	PAPER NUMBER
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3735

MAIL DATE	DELIVERY MODE
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01/03/2013

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<i>Applicant-Initiated Interview Summary</i>	Application No. 12/850,547	Applicant(s) PHILLIPS ET AL.	
	Examiner JOSHUA D. LANNU	Art Unit 3735	

All participants (applicant, applicant's representative, PTO personnel):

(1) JOSHUA D. LANNU. (3) KRISTIN HAVRANEK.

(2) JOHN LACYK. (4) _____.

Date of Interview: 19 December 2012.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☐ No.
If Yes, brief description: _____.

Issues Discussed ☐ 101 ☒ 112 ☒ 102 ☐ 103 ☐ Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: 2, 12, and 22.

Identification of prior art discussed: US 6488617 - KATZ.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Examiners and Applicant's counsel discussed language in claim 2 regarding differences in moving vs influencing intrinsic frequencies and Q - factors. Potential issues regarding language in claims 12 and 22 were pointed out by the Examiners. Examiners will get back to Applicant's counsel in regards to how to claim the programmed method in the apparatus claims.

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/John P Lacyk/ Primary Examiner, Art Unit 3735	/J. D. L./ Examiner, Art Unit 3735
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Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

ELECTRONICALLY FILED ON JANUARY 18, 2013

**Attorney Docket No. 35784-706.201
PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: James William Phillips et al.

Serial Number: 12/850,547

Filing Date: August 4, 2010

Title: SYSTEMS AND METHODS FOR
MODULATING THE ELECTRICAL
ACTIVITY OF A BRAIN USING NEURO-
EEG SYNCHRONIZATION THERAPY

Group Art Unit: 3735

Examiner: Lannu, Joshua Daryl Deanon

Confirmation No: 1056

Customer No. 021971

AMENDMENT IN RESPONSE TO FINAL OFFICE ACTION

MAIL STOP RCE

Commissioner for Patents

P.O. Box 1450

Alexandria VA 22313-1450

Commissioner:

This paper responds to the Final Office Action dated July 19, 2012 setting an initial due date of October 19, 2012. Applicants filed their Response on September 10, 2012 and an Advisory Action issued thereafter on October 12, 2012. A Petition for Extension of Time is therefore requested for a reply within the third month and the fee set forth under 37 C.F.R. §1.17(a)(3) is electronically submitted herewith. Applicants also submit herewith a Request for Continued Examination (RCE) and the appropriate fee. Applicants believe that the fees submitted herewith are sufficient. However, in the event that Applicants are incorrect, please charge any necessary fees to Deposit Account No. 23-2415, referencing Docket No. 35784-706.201.

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 7 of this paper.

Conclusion begins on page 11 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings of claims in this application. Applicant reserves the right to pursue any subject matter of any canceled claims in this or any other appropriate patent application. Support for these claims is provided in the remarks following the listing of claims.

1. (Currently Amended) A method of treating Parkinson's disease, treating coma, treating post traumatic stress disorder (PTSD), treating amblyopia, and/or enhancing cognitive performance, in a subject, comprising:

(a) adjusting output of a magnetic field to a setting that is operable to do one or more of the following:

- ~~influence~~ move an intrinsic frequency of a specified EEG band of the subject toward a target intrinsic frequency of the specified EEG band,
- ~~influence~~ move a Q-factor of the intrinsic frequency toward a target Q-factor,
- ~~influence~~ move a coherence value of intrinsic frequencies among multiple sites in a brain of the subject within a specified EEG band toward a target coherence value wherein if the coherence value is higher than the target coherence value, applying at least two asynchronous magnetic fields close to the head of the subject, and wherein if the coherence value is lower than the target coherence value, applying at least one synchronized magnetic field close to a head of the subject; and
- ~~influence~~ move an EEG phase between two sites in the brain of a subject of a specified EEG frequency toward a target EEG phase of the specified EEG frequency wherein the magnetic field comprises one or more magnetic field generators that are of the same frequency and are in-phase with each other, of the same frequency and out of phase with each other, or a combination thereof; and

(b) applying said magnetic field close to a head of the subject.

2. (Currently Amended) A method of treating Parkinson's disease, treating coma, treating post traumatic stress disorder (PTSD), treating amblyopia, and/or enhancing cognitive performance in a subject, comprising ~~adjusting~~ moving at least one of:
 - an intrinsic frequency of a brain of the subject within a specified EEG band toward a pre-selected intrinsic frequency within the same specified EEG band and
 - a Q-factor of the intrinsic frequency,

by applying a magnetic field close to a head of the subject, wherein the magnetic field comprises at least one of (a) a single target frequency within the specified EEG band; (b) a plurality of frequencies within the specified EEG band; and (c) the intrinsic frequency of a brain of the subject within the specified EEG band ~~wherein adjusting the intrinsic frequency comprises influencing a Q-factor of the intrinsic frequency.~~
3. (Original) The method of claim 1 or 2, further comprising the step of measuring EEG data of the subject after the applying step.
4. (Original) The method of claim 1 or 2, further comprising the steps of: adjusting frequency of said magnetic field based on the EEG data of the subject; and repeating the applying step with an adjusted frequency.
5. (Original) The method of claim 1 or 2, wherein the applying of the magnetic field applies the magnetic field to a diffuse area in a brain of the subject.
6. (Original) The method of claim 1 or 2, wherein the magnetic field is generated by movement of at least one permanent magnet.
7. (Original) The method of claim 6, wherein the strength of the at least one permanent magnet is from about 10 Gauss to about 4 Tesla.
8. (Original) The method of claim 7, wherein the distance between the at least one permanent magnet and the subject is from about 1/32 in to about 12 in.
9. (Original) The method of claim 1 or 2, wherein the step of applying the magnetic field is for about 5 minutes to about two hours.

10. (Original) The method of claim 1 or 2, further comprising repeating the applying step after an interval about 6 hours to about 14 days.
11. (Original) The method of claim 1 or 2, further comprising: (a) locating a first electrode operable to detect electrical brain activity on the subject in at least one of an area of low electrical resistivity on a subject, and an area with substantially no electrical impulse interference on a subject; (b) locating a second electrode operable to detect a reference signal on the subject; and (c) determining the intrinsic frequency from the electrical brain activity detected by the first electrode and the reference signal detected by the second electrode.
12. (Currently Amended) A device for use in treating Parkinson's disease, treating coma, treating post traumatic stress disorder (PTSD), treating amblyopia, and/or enhancing cognitive performance in a subject, comprising: a means for applying a magnetic field to a head of a subject; whereby the means for applying the magnetic field comprises

a first processor that controls the application of the magnetic field and

the first processor or a second processor that moves is configured to influence at least one of:
 - (a) an intrinsic frequency of a brain of the subject within a specified EEG band;
 - (b) a Q-factor of an intrinsic frequency of the brain of the subject within a specified EEG band;
 - (c) a coherence value of intrinsic frequencies among multiple sites in the brain of the subject within a specified EEG band wherein if the coherence value is higher than a pre-selected coherence value, applying at least two asynchronous magnetic fields close to the head of the subject, and wherein if the coherence value is lower than the pre-selected coherence value, applying at least one synchronized magnetic field close to a head of the subject; and
 - (d) a EEG phase between two sites in the brain of the subject of a specified EEG frequency wherein the magnetic field comprises a first magnetic field that is in-phase with a second magnetic field or a first magnetic field that is out of phase with a second magnetic field.

Attorney Docket No. 35784-706.201

13. (Original) The device of claim 12, comprising at least one permanent magnet.
14. (Original) The device of claim 12, wherein the magnetic field is generated by movement of at least one permanent magnet.
15. (Original) The device of claim 12, wherein the movement of the at least one said magnet is at a frequency between about 0.5 Hz and about 100 Hz.
16. (Original) The device of claim 12, wherein said movement comprises at least one of rotational motion, linear motion, and swing motion.
17. (Original) The device of claim 12, wherein said movement generates an alternating magnetic field.
18. (Original) The device of claim 12, further comprising logic that controls the frequency to be any frequency between about 0.5 Hz and about 100 Hz in increments of about 0.1 Hz.
19. (Original) The device of claim 12, further comprising logic that automatically changes the frequency in response to EEG readings of a subject during treatment.
20. (Original) The device of claim 12, further comprising logic that calculates information from EEG data collected from the subject within a specified EEG band, wherein said information comprises at least one of items listed below: (a) at least one intrinsic frequency; (b) Q-factor of the at least one intrinsic frequency; (c) a coherence value of intrinsic frequencies; (d) an EEG phase; and (e) any combination thereof.
21. (Previously Presented) The device of claim 12, further comprising: (a) a first electrode operable to detect electrical brain activity; and (b) a second electrode operable to detect a reference signal; wherein the first electrode adapted to be located on the subject in at least one of: an area of low electrical resistivity on a subject, and an area with substantially no electrical impulse interference on a subject, and wherein the second electrode adapted to be located on the subject.
22. (Currently Amended) A device for treating Parkinson's disease, treating coma, treating post traumatic stress disorder (PTSD), treating amblyopia, and/or enhancing cognitive

performance in a subject, comprising a magnetic field generator configured apply a magnetic field close to a head of the subject, wherein the magnetic field generator comprises

a first processor that controls the application of the magnetic field and

the first processor or a second processor that moves

- an intrinsic frequency of a specified EEG band of the subject within the specified EEG band toward a target intrinsic frequency in the specified EEG band,
- a Q-factor of the intrinsic frequency,
- a coherence value of intrinsic frequencies among multiple sites in a brain of the subject within a specified EEG band toward a target coherence value wherein if the coherence value is higher than the target coherence value, applying at least two asynchronous magnetic fields close to the head of the subject, and wherein if the coherence value is lower than the target coherence value, applying at least one synchronized magnetic field close to a head of the subject; and
- an EEG phase between two sites in the brain of a subject of a specified EEG frequency toward a target EEG phase of the specified EEG frequency wherein the magnetic field comprises one or more magnetic field generators that are of the same frequency and are in-phase with each other, of the same frequency and out of phase with each other, or
- a combination thereof

~~— and wherein the magnetic field is chosen in order to adjust a Q factor of an intrinsic frequency of a brain of the subject within a specified EEG band by, wherein the magnetic field comprises at least one of (a) a single target frequency within the specified EEG band; (b) a plurality of frequencies within the a specified EEG band; and (c) the intrinsic frequency of a brain of the subject within the a specified EEG band.~~

23. (New) The device of claim 22, wherein the magnetic field comprises at least one of (a) a single target frequency within the specified EEG band; (b) a plurality of frequencies within the a specified EEG band; and (c) the intrinsic frequency of a brain of the subject within the a specified EEG band.

REMARKS

The following remarks are in response to the Examiner's Final Office Action mailed on July 19, 2012 and Advisory Action of October 12, 2012. Claims 1, 2, 12, and 22 are amended. Claim 23 is new. Support for claim amendments can be found in the application as filed, and specifically, Claim 23 support can be found in Claim 22 as originally filed. Claims 1-23 are pending.

Applicants wish to sincerely thank Examiner Lannu for indication that Applicants' Office Action Response of September 10, 2012 overcame the provisional obviousness type double patenting rejection of the Final Office Action mailed on July 19, 2012. Reconsideration of the Amended Claims is respectfully requested in light of the following remarks.

Interview Summary

Applicants wish to thank the Office for the Telephone Interview on December 19, 2012, which included Applicants' representative, Kristin Havranek, Examiner Joshua Lannu and Primary Examiner John Lacyk, and for the follow up conversation on January 15, 2013, which included Applicants' representative, Kristin Havranek and Examiner Joshua Lannu. The substance of the Advisory Action of October 12, 2012, the Office Action Response of September 10, 2012, and the Final Office Action of Final Office Action mailed on July 19, 2012 were discussed during the Interview and follow up conversation, and it was agreed that the amendments presented herein would place all claims in condition of allowance, for the reasons set forth below, at least.

Double Patenting Rejection

Claims 1 and 3-11 have been provisionally rejected as being unpatentable over claims 1-4 and 6-14 of copending Application No. 12/237,328. Claims 12-16 and 18-21 have been provisionally rejected as being unpatentable over claim 26-33 of copending Application No. 12/237,319. In response, on September 10, 2012, Applicants submitted terminal disclaimers which obviated the provisional nonstatutory double patenting rejections. Withdrawal of such rejections is respectfully requested. As there are no rejections of Claim 1 other than the provisional nonstatutory double patenting rejections, Applications submit that the terminal disclaimers filed puts this claim, at least, in condition of allowance. Thus, Applicants thank the Examiner for the indication of allowance of Claim 1.

Claim Rejections – 35 USC § 102

Claims 2-5 and 22 have been rejected under 35 U.S.C. 102 as being anticipated by US 6,488,617 (“Katz”).

Katz fails to anticipate the elements of Claims 2-5 and 22, at least. Katz describes a feedback system, which in real time, tries to move a subject from a current brain state into a desired brain state via magnetic stimulation. Brain states targeted in Katz are categorized based on the level of alertness of the subject. (Col. 1, line 14 to 34). These states include sleep states associated with brain wave frequencies in the delta and theta ranges of 1.5 to 3.5 Hz and 3.5 to 7 Hz, respectively, a relaxed state associated with brain wave frequencies in the alpha range of 7.5 to 12.5 Hz, and an excited state associated with brain wave frequencies in the beta range of 12.5 to 20 Hz (*Id.*, *See also*, Col. 6, lines 16-35). Thus, each state of Katz is within a different EEG band, and Katz tries to move the subject from one state (in one band) to another state (in another band). At least the following distinctions can be made from the present claims.

With respect to Claim 2, Katz fails to teach or suggest “moving at least one of: an intrinsic frequency of a brain of the subject within a specified EEG band toward a pre-selected intrinsic frequency within the same specified EEG band and a Q-factor of the intrinsic frequency.”

In contrast, Katz targets a desired brain state, which encompasses a range of frequencies in multiple bands. Claim 2 of the present invention targets a pre-selected intrinsic frequency, not a state encompassing a range of frequencies. The Office Action tacitly acknowledges this difference by referring to the desired state of Katz and frequencies in each state, as opposed to a particular pre-selected frequency as is claimed.

Further, Claim 2 of the present invention recites moving the subject’s intrinsic frequency in a specified EEG band toward a pre-selected intrinsic frequency of the same EEG band. On the other hand, Katz’s only intention and goal is to move a subject from a current brain state into a desired brain state. Since the brain states correlate to separate EEG bands in Katz (i.e. from relaxed in the alpha band to sleep in the delta or theta band), Katz’ methods and devices move the brain waves from one band to another.

Alternatively, or additionally, Claim 2 moves a Q factor of an intrinsic frequency. As described and shown in the instant specification (for example at paragraphs [0300], [0326] and in Figure 12, at least), a Q-factor is a measure of the distribution around the frequency within a single

EEG band. Changing a frequency from one band to another band does not inherently or necessarily change the Q-factor, which is essentially a distribution around a particular frequency. In contrast, Katz makes no effort or disclosure regarding the Q-factor or other distribution of frequencies around an intrinsic frequency.

The Office Action points to Katz Column 6 lines 16-61 and states “Katz states that a higher magnitude magnetic field increases the focus of a mean frequency, which is the equivalent of modifying the bandwidth of an intrinsic frequency to a preselected bandwidth.” On the contrary, Katz’s reference to focus refers to the focal area of the brain, and not a focus of a mean frequency. Katz actually says that “a key component [of the magnetic field] is field strength. Greater magnitude [of field strength] implies more influence on the intended [focal area of the brain], although the size of that [focal area] will also increase as the magnitude [of field strength] increases” in Column 6 lines 16-61. This makes sense, since Katz uses multiple magnets having unique and varying frequencies, magnitudes, positions and durations applied to the subject’s head. Thus, Katz recognizes that field strength is one parameter (of several) that may be used in order to achieve its goal of moving a subject from a state in one EEG band to a state in another EEG band; however, Katz neither discloses nor suggests “moving ... a Q-factor of the intrinsic frequency.”

Likewise, for similar reasons as noted with regard to Claims 2, Katz simply fails to disclose or suggest all of the elements of each of Claims 3-5, at least.

Furthermore, neither does Katz disclose or suggest a magnetic field generator of Claim 22 comprising a processor “that moves an intrinsic frequency of a specified EEG band of the subject within the specified EEG band toward a target intrinsic frequency in the specified EEG band, a Q-factor of the intrinsic frequency, a coherence value of intrinsic frequencies among multiple sites in a brain of the subject within a specified EEG band toward a target coherence value wherein if the coherence value is higher than the target coherence value, applying at least two asynchronous magnetic fields close to the head of the subject, and wherein if the coherence value is lower than the target coherence value, applying at least one synchronized magnetic field close to a head of the subject; and an EEG phase between two sites in the brain of a subject of a specified EEG frequency toward a target EEG phase of the specified EEG frequency wherein the magnetic field comprises one or more magnetic field generators that are of the same frequency and are in-phase with each other, of the same frequency and out of phase with each other, or a combination thereof.”

Based on this, at least, Applicants submit the independent Claims 1, 2 (as amended), and 22 (as amended) and all claims dependent therefrom, are in condition for allowance and advancement to allowance is earnestly solicited.

Claim Rejections - 35 USC § 103

Claim 6 has been rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,488,617 (“Katz”) as applied to claim 2, and further in view of 6,001,055 (“Souder”). Claims 7 and 8 have been rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,488,617 (“Katz”) and US 6,001,055 (“Souder”) as applied to claim 6, and further in view of US 5,667,469 (“Zhang”). Claims 9 and 10 have been rejected under 35 U.S.C. 103(a) as being unpatentable over 6,488,617 (“Katz”) as applied to claim 2, and further in view of US 5,788,624 (“Lu”). Claim 11 has been rejected under 35 U.S.C. 103(a) as being unpatentable over 6,488,617 (“Katz”) as applied to claim 2, and further in view of US 3,821,949 (“Hartzell”).

To establish a *prima facie* case of obviousness, the cited art itself or “the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]” at the time of the invention are to have taught or suggested the claim elements. *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1742 (2007); *See also* MPEP § 2143.03. Thus, the Examiner must make “a searching comparison of the claimed invention – including all its limitations – with the teaching of the prior art.” *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995). As such, “obviousness requires a suggestion of all limitations in a claim.” *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)).

As noted above with regard to Claims 2, Katz fails to disclose or suggest all of the elements in each of the noted independent claim. None of Souder, Zhang, Lu, or Hartzell, whether considered alone or in any combination with Katz or any other reference make up for the deficiencies of Katz, as noted above. Thus, Applicants submit that independent Claim 2, and all claims dependent therefrom, are in condition of allowance. Advancement to allowance is earnestly solicited for all of Claims 1 to 11.

Claims 12-21 have been rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,001,055 (“Souder”) and in view of US 6,488,617 (“Katz”). On the contrary, Souder fails to

disclose or suggest a device comprising “a means for applying a magnetic field to a head of a subject; whereby the means for applying the magnetic field comprises a first processor that controls the application of the magnetic field and the first processor or a second processor that moves at least one of: (a) an intrinsic frequency of a brain of the subject within a specified EEG band; (b) a Q-factor of an intrinsic frequency of the brain of the subject within a specified EEG band; (c) a coherence value of intrinsic frequencies among multiple sites in the brain of the subject within a specified EEG band wherein if the coherence value is higher than a pre-selected coherence value, applying at least two asynchronous magnetic fields close to the head of the subject, and wherein if the coherence value is lower than the pre-selected coherence value, applying at least one synchronized magnetic field close to a head of the subject; and (d) a EEG phase between two sites in the brain of the subject of a specified EEG frequency wherein the magnetic field comprises a first magnetic field that is in-phase with a second magnetic field or a first magnetic field that is out of phase with a second magnetic field” as required in Claim 12, as amended, and thus, required in any claim dependent therefrom. Katz fails to make up for the deficiencies of Souder as noted with regard to Claims 2 or 22, above. Based on this, at least, Applicants submit the independent Claim 12, as amended, and all claims dependent therefrom, are in condition for allowance and advancement to allowance is earnestly solicited.

Attorney Docket No. 35784-706.201

CONCLUSION

In light of the remarks set forth above, Applicants believe that the pending claims are under condition for allowance. Applicants respectfully solicit the Examiner to expedite the prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned.

The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 23-2415 (Attorney Docket No. 35784-706.201).

Respectfully submitted,

Date: January 18, 2013

By: /Kristin Havranek/
Kristin Havranek
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Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No.	Applicant(s)	
	12/850,547	PHILLIPS ET AL.	
	Examiner	Art Unit	
	JOSHUA D. LANNU	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the communication received on 1/29/2013 and the interview on 2/20/2013.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
3. ☐ The allowed claim(s) is/are _____. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 2. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>1/18/2013</u> | 6. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| 3. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 7. <input type="checkbox"/> Other _____. |
| 4. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>2/20/2013</u> . | |